

# BioScience

## JOURNAL

AUTUMN 2014



## Ebola

*the debate between  
clinical need and  
economic reality*

### Life or Death

*The importance of Cold  
Chain Supply*


### Crime Scene

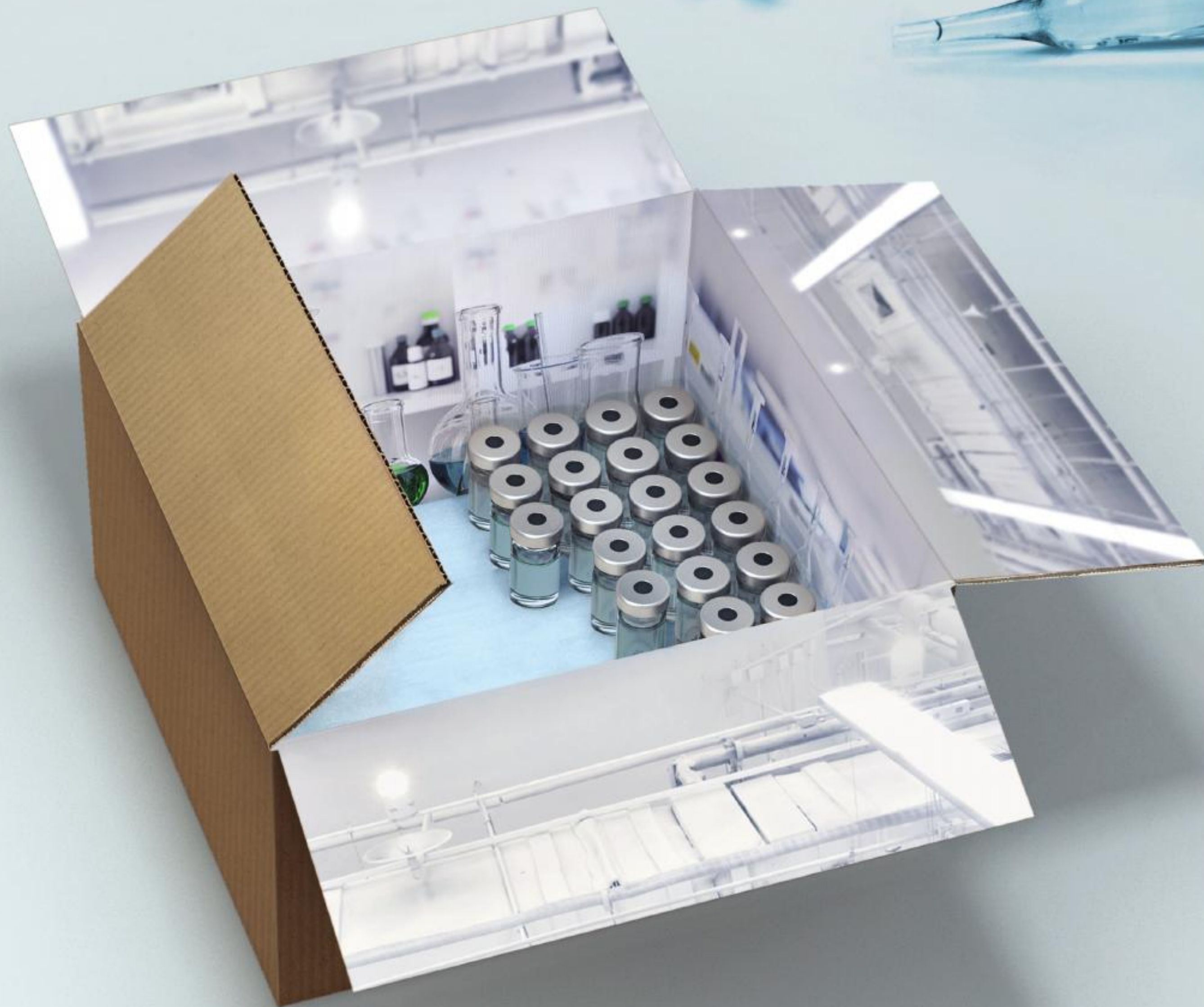
*International efforts target  
improvements in food safety*

### Sports Science

*When the worlds of sport and  
medicine collaborate*



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# Welcome



**John Dean**  
Editor in chief

## Counting the cost of a cure

There is nothing like an outbreak of a frightening disease to get the world's media excited and the recent ebola crisis in West Africa has proved that to be the case.

Like all such outbreaks, there is a tipping point when it goes from something happening under the media's radar, something in countries which do not illicit much in the way of global interest, to something that is suddenly big, worldwide news.

That certainly happened with ebola, not so much because death counts were rising in West Africa but more, you have to say, because it was possible that the virus could jump oceans on commercial aircraft and threaten people in the western world.

Suddenly, news crews descended on the affected areas to document what had become a state of emergency. Cue a plethora of scare stories as well as, let's be fair, a lot much more considered journalism as well.

What makes ebola frightening, and what piques the interest of the media, is the drastic way that the virus afflicts patients and the fact that it is regarded as incurable.

However, it may be curable, a debate which inevitably creates a sense of uneasiness. The signs are there that effective drug-based treatment is possible but this is where cutting-edge science and hard-edged economics come into conflict.

The problem is that coming up with new drugs is expensive - very expensive.

In addition to examining the ebola debate, this edition of The Bioscience Journal also examines the largely unheralded contribution to medical advancement made by 'ordinary' people prepared to take part in clinical research.

Magazines such as ours routinely report on amazing breakthroughs, cures, therapies, wonder-drugs, but they simply would not be possible without people being prepared to take part in clinical trials and research projects.

The benefits are there for all to see - illnesses rendered virtually extinct, conditions controlled like never before, the quality of lives improved, lifespans prolonged - and yet many of us are still reluctant to take part. In this edition, we look at what can be done to break down the barriers.

I have talked in this editorial about the costs connected to drug development - in the case of taking part in trials can we really afford not to?

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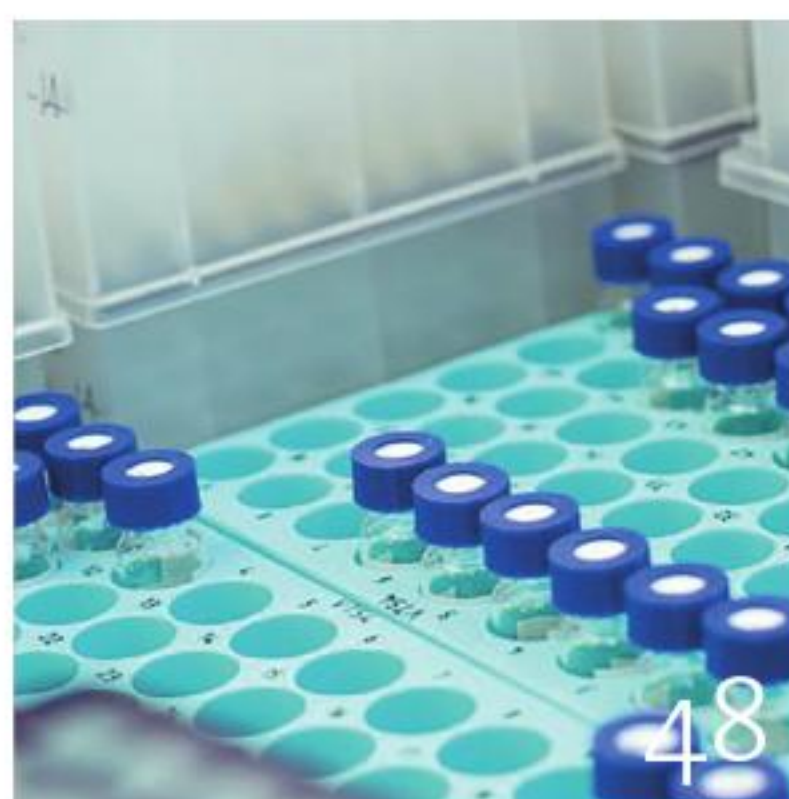
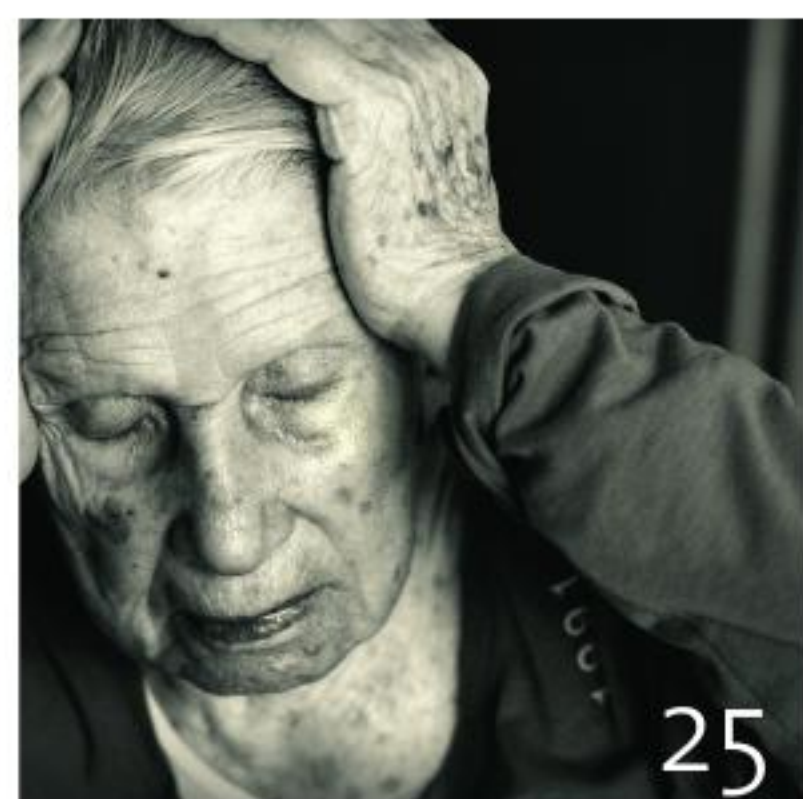
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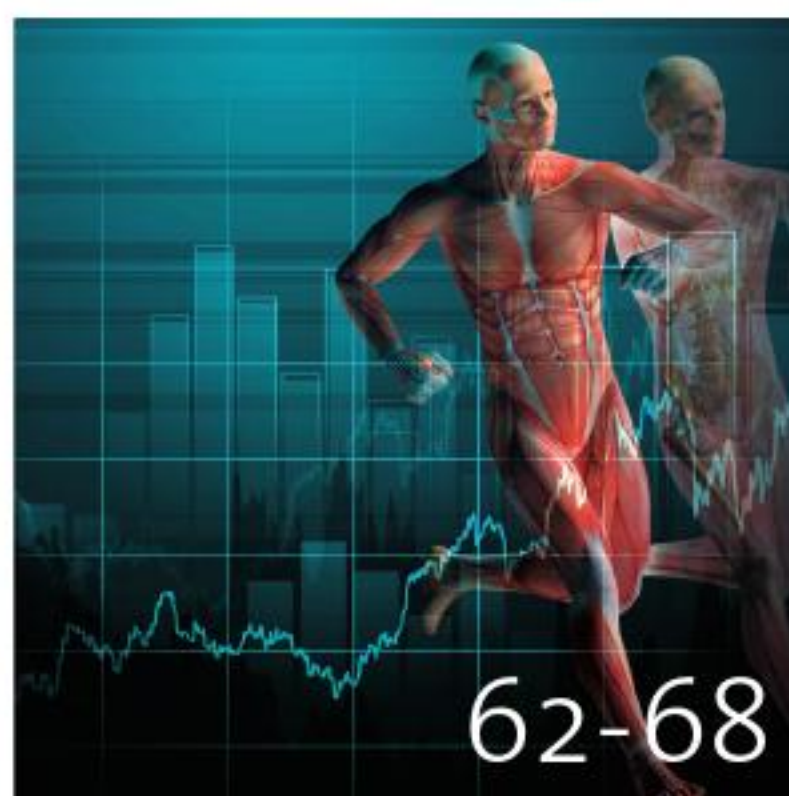
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# Guest Foreword



**George Freeman**  
Minister for Life Sciences

## UK – A global leader for life sciences

In the wake of the recession, and with the UK still carrying a substantial fiscal deficit, the fundamental challenge of our age is how to get more from less in the public sector and how we can use our knowledge economy to drive our export and investment opportunities. As the world faces a global grand challenge to 'feed, fuel and heal' a burgeoning population of 9 billion by 2050, I believe our bioscience economy has a key role to play in unlocking the 'smart growth' we all need.

In the 3 key challenges of food, medicine and energy, bioscience is opening up huge opportunities and demonstrating our ability to unleash productivity through innovation. This is seen most obviously in health. With a rising elderly population and an ever expanding range of expensive new drugs, technologies and treatments, the cost of healthcare is already the biggest driver of the structural deficit. The question all ageing European societies are confronting is; Can we make our healthcare ecosystem both more supportive of innovation so that every health pound spent delivers both smarter health and new economic opportunities.

The answer, I believe, is by embracing the new dawn of 21st-century medicine brought about through our life sciences sector. With our world-leading research base and world class companies, the life sciences are already a major UK industry. There are nearly 5,000 companies in the UK life sciences sector, employing around 180,000 skilled professionals.

As the first ever Minister for Life Sciences, I believe the UK can become a global hub for 21st-century life sciences, stimulating investment and benefitting patients. This was the vision we set out in the flagship Life Sciences Industrial Strategy in 2011 – which I helped design as Government Adviser, and am now tasked with implementing as Minister.

Two fundamental technologies are transforming life sciences; genomics and

informatics. With the rise of genomic technologies, 21st century healthcare is increasingly moving from one-size-fits-all 'blockbuster' model to a new age of personalised medicine, with drugs designed around our genetic profile. By harnessing the UK's unmatched strength in research, the NHS, medical charities and vibrant and innovative companies, we are already at the forefront of this change, transforming the way healthcare is delivered.

That's why the Government has invested £100 million to sequence 100,000 whole genomes over the next three to five years. Genomics England is leading this initiative, which will enable the UK to play a world-leading role in the genomics biomedical revolution.

Through our funding and setting up of the Catapult centres, investment in Big Data and protection of science funding for the Biotechnology and Biological Sciences Research Council, we are backing Bioscience as central to our long term economic plan. I look forward to doing all I can to show how bioscience can benefit us all.





# Flu vaccine programme has impact



*Early results from the 2013 to 2014 child flu vaccine pilot programme suggest a positive impact on levels of flu in the United Kingdom.*

Public Health England (PHE), which launched the pilot programme last year, says that the initial results are encouraging.

In 2012, the Joint Committee on Vaccination and Immunisation advised extending the national flu immunisation programme to all children from the age of two to less than 17 years.

In addition to protecting healthy children from flu, the extension aimed to reduce the spread of flu and protect younger siblings, grandparents and those who are at increased risk of becoming seriously ill from flu.

As a first step in the extension of the programme, all children aged two and three years were offered flu vaccination last year, while children aged between four and 11-years-old were vaccinated in seven pilot areas.

Pilots took place in Bury, Cumbria, Gateshead, Leicester, East Leicestershire and Rutland, and the London Boroughs of Havering and Newham and South East Essex. A total of 104,792 primary age children received at least one dose of a nasal spray flu vaccine,

or a needle vaccine for the small number of children unable to receive the nasal spray vaccine. This represents an overall uptake of 52.5% in the target group.

Despite the low flu activity in 2013 to 2014, early results, although statistically non-significant, suggest a positive impact.

Results were obtained from a range of surveillance indicators including GP consultations for influenza-like illness, swab positivity in primary care, laboratory confirmed hospitalisations and percentage of respiratory emergency department attendances.

The influenza rate in primary care in pilot areas was 8.5% compared to 16.2% in non-pilot areas. The proportion of emergency department respiratory attendances was 5.5% in pilot compared to 8.7% in non-pilot areas.

From September 2014 vaccination against flu will be offered to all children aged two to four years of age. The geographical pilots for primary school children established in 2013 to 2014 will continue and a number of additional

pilots for secondary school age children in years 7 and 8 (ages 11 to 12) will also begin in some areas.

Dr. Richard Pebody, study author and flu expert at PHE, said: "These early results of the uptake and impact of the first year of the childhood flu vaccine programme are encouraging and the uptake levels already achieved in primary school age children in the pilot areas are positive."

"Despite the season being of relatively low intensity, these early findings already suggest a likely impact of vaccinating school-age children on levels of circulating flu, which is encouraging for the on-going roll-out."

Dr Paul Cosford, Director for Health Protection and Medical Director at PHE, said: This is an important addition to the national programme and is being carefully planned. The pilots are helping us to understand the best way to implement the programme nationally, ensuring that we can set up a successful and sustainable programme, vaccinating children and young people to protect them and the wider population."



## Let there be light

University researchers have identified a new type of light sensor that could allow medical imaging, via low cost cameras.

The team from the University of Surrey have developed a 'multispectral' light sensor that detects the full spectrum of light, from ultra-violet to visible and near infrared light.

Near infrared light can be used to perform non-invasive medical procedures, such as measuring the oxygen level in tissue and detecting tumours.

## Childhood factors that influence adult health

Research from the University of Glasgow has suggested that key factors in early life can reveal a lot about health in later life.

The team measured health and mental well-being in 6,285 adults from Aberdeen in Scotland, including the type of area they lived in, the type of school they attended and family circumstances when they were aged nine.

Results suggested that those who lived in poorer areas as children had worse health as adults.

## Prize targets bacteria challenge

The search for a tool to differentiate between bacterial and viral infections has won the £10m Longitude prize.

Incorrect use of antibiotics to treat viral infections gives bacteria the chance to develop resistance without providing any benefit to the patient.

Now, the Longitude Committee is developing the challenge criteria that will set out what people need to do to win the prize. Ideas can be submitted from the Autumn

# 'A step closer to diagnosing early Parkinson's'



## Research funded by Parkinson's UK has brought medical researchers closer to ways of diagnosing the early stage of the condition.

Diagnosing Parkinson's is difficult and one of the big problems for clinicians is identifying the medical indicators.

Now, a research team, who are part of the Monument Discovery Project at University of Oxford, have used a new imaging technique to diagnose early stage Parkinson's with an accuracy of 85%.

They used resting state fMRI – where people are required to stay still in an MRI scanner for a longer period of time – to compare levels of 'connectivity', or strength of brain networks in the basal ganglia, part of the brain known to be involved in Parkinson's.

When this data was compared to those without Parkinson's, the researchers were able to set a standard for level of connectivity to diagnose early stage Parkinson's.

Claire Bale, Research Communications Manager at Parkinson's UK, said: "This new research takes us one step closer to diagnosing Parkinson's at a much earlier stage – one of the biggest challenges facing research into the condition.

"By using a new, simple scanning technique the team at Oxford have been able to study levels of activity in the brain which may suggest that Parkinson's is present.

"One person every hour is diagnosed with Parkinson's in the UK. We hope that the researchers are able to continue to refine their test so that it can one day be part of clinical practice."





# Images deepen understanding of stress in the womb

*Fetuses are more likely to show left-handed movements in the womb when their mothers are stressed, according to new research.*

Researchers at Durham and Lancaster universities say that their findings are an indicator that maternal stress could have a temporary effect on unborn babies.

However, the researchers emphasised that their study was not evidence that maternal stress led to fixed left-handedness in infants after birth.

They said that some people might be genetically predisposed to being left-handed and that there are examples where right and left-handedness can switch throughout a person's life.

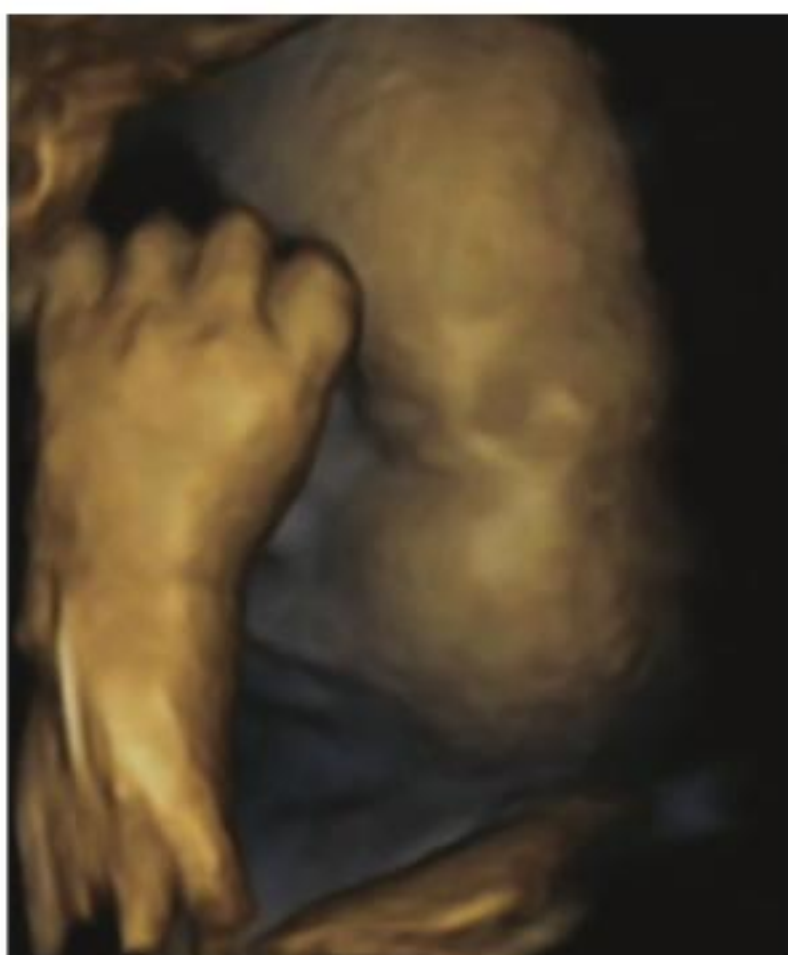
Using 4d ultrasound scans, the researchers observed 57 scans of 15 healthy fetuses, recording 342 facial touches.

The fetuses were scanned at four different stages between 24 and 36 weeks of pregnancy. Researchers also asked the mothers of these babies how much stress they had experienced in the four weeks between each of the scans.

The researchers found that the more stress mothers reported, the more frequently fetuses



**Fetus at 32 weeks touching its mouth with its left hand**  
Images from Dr Nadja Reissland, Durham University



touched their faces with their left hands. They added that a significant number of touches by the fetuses of stressed mothers were done with their left, rather than right hands.

As right-handedness is more common in the general population, the researchers had expected to see more of a bias towards right-handed movements in the fetuses as they grew older.

The high percentage of left-handed behaviour, observed only when mothers reported being stressed, led them to conclude that maternal stress has an effect on the behaviour of the babies they scanned.

Lead author of the study, Dr Nadja Reissland, in Durham University's Department of Psychology, said: "Our research suggests that stressed mothers have fetuses who touch their face relatively more with their left hand.

"This suggests maternal stress could be having an effect on the child's behaviour in the womb

and highlights the importance of reducing maternal stress in pregnancy.

"Such measures may include increased emphasis on stopping stressful work early, the inclusion of relaxation classes in pre-natal care and involvement of the whole family in the pre-natal period.

"While we observed a higher degree of left-handed behaviour in the fetuses of stressed mothers than had been expected, we are not saying that maternal stress leads to a child becoming left-handed after birth, as there could be a number of reasons for this.

"The research does suggest, however, that a fetus can detect when a mother is stressed and that it responds to this stress."

Professor Brian Francis, of Lancaster University, said: "Overall, there was no consistent handedness preference being shown by the fetuses, with most fetuses switching in preference at least once over the four scans."



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An *Anopheles stephensi* mosquito shortly after obtaining blood from a human

## Putting the bite on disease

*UK holidaymakers are being urged to use insect repellent to protect themselves against bites and the diseases they can spread as travel to tropical countries rises among Britons.*

Scientists from repellent testing facility arctec at the London School of Hygiene & Tropical Medicine recently launched the Bug Off campaign to highlight the issue.

According to analysis by experts from the School of Overseas Travel, the number of visits by Britons to tropical countries went up by two million between 2002 and 2012 (4.02m to 6.03m).

The scientific team who studied the effects of preventatives recommend applying repellents containing 20-50% DEET, a repellent applied to the skin to repel biting insects, when in countries with diseases spread by insects, such as malaria and dengue fever.

Although medicine and vaccines can prevent some diseases, they don't prevent them all; in those cases, stopping the bite in the first place is seen as the best line of defence.

In their analysis of animal research and other safety assessments carried out previously,

the researchers concluded that there is no evidence of association between severe adverse events and recommended DEET use.

They looked at case reports of people suffering encephalopathy (a brain condition) following exposure to DEET in the 1980s. The researchers stated that, even when allowing for underreporting, "the incidence of 14 reported cases of DEET-associated encephalopathy since 1957 is small when considered against the context of an estimated 200 million applications of DEET worldwide each year".

Dr James Logan, Senior Lecturer in Medical Entomology at the London School of Hygiene & Tropical Medicine and Director of arctec, said: "Biting arthropods can transmit a whole range of diseases to humans and it is vital to protect ourselves.

"Vaccines and treatments are available for some diseases but not all and so the best way to keep as safe as possible is to use an insect

repellent containing DEET and reapply it regularly.

"We want people to enjoy their holidays and tropical trips – we don't want them ruined by illness so we want to do all we can to help inform and educate people about the facts rather than the many myths surrounding this issue."

Dr Ron Behrens, Consultant in Travel Medicine and Senior Lecturer at the London School of Hygiene & Tropical Medicine, said: "Travellers often underestimate the need for and application of repellents. I always encourage them to take along enough supplies of repellent and always carry a bottle with them when out and about to maintain protection throughout the day and evening.

"If bites do happen, make sure they don't become infected by applying an antiseptic and try to avoid scratching them."





## Learning more about the human GPS

The human brain may have its own GPS system, according to new research funded by the Wellcome Trust.

The study found that one part of the brain calculates the straight line to a destination but during travel a different area computes the distance along the path to get there.

Dr Hugo Spiers and his team at UCL came up with their findings by using film footage to recreate the streets of Soho in London inside an MRI scanner.

Those taking part in the study were asked to navigate through the district while their brain activity was monitored.

They found that activity in the entorhinal cortex, a region essential for navigation and memory, was used in working out the straight-line distance but the posterior hippocampus, known for its role in navigation and memory, became active when keeping track of the path.

Dr Spiers said: "Our results indicate that it is the daily demand on processing paths in

their posterior hippocampus that leads to the impressive expansion in their grey matter.

"These findings help us understand the mechanisms by which the hippocampus and entorhinal cortex guide navigation. The research is also a substantial step towards understanding how we use our brain in real world environments, of which we currently know very little."

Dr John Williams, Head of Clinical Activities, Neuroscience and Mental Health at the Wellcome Trust, said: "These findings provide insight into the underlying biology of mental health conditions which affect our memory.

"The hippocampus and entorhinal cortex are among the first regions to be damaged in the dementia associated with Alzheimer's disease and these results provide some explanation as to why such patients struggle to find their way and become lost. Combining these findings with clinical work could enable medical benefits in the future."

## Drug offers hope for COPD sufferers

UK company Domainex has announced that its lead compound has demonstrated a more potent effect in a model of chronic obstructive pulmonary disease (COPD) than roflumilast or a p38 inhibitor.

Dr Trevor Perrior, Research Director at Domainex, said: "These are very exciting results which suggest that our programme could lead to an oral drug for the treatment of COPD with a much better anti-inflammatory effect than existing medicines."

## Grant for researcher

A researcher from the University of Manchester has received funding from Arthritis Research UK for work that will help identify the genes involved in developing rheumatoid arthritis.

Dr Stephen Eyre will use his three-year research grant of £160,194 to build further on a recent genetics study which examined changes to the DNA sequence.

## Blood test could identify Alzheimer's

UK scientists have identified ten proteins in the blood which can predict the onset of Alzheimer's, which is seen as a significant step towards developing a blood test for the disease.

The study, led by King's College London and UK proteomics company Proteome Sciences plc, was based on the analysis of more than 1,000 people and is the largest of its kind to date.

## £48m for biomedical research projects

The UK Government has announced £48 million of new investment in biomedical research.

More than 70 projects have been chosen as part of the Biomedical Catalyst, a scheme run jointly by the Medical Research Council and the UK's innovation agency the Technology Strategy Board.

Projects include:

- Biomedical Catalyst funding will enable researchers at the University of Edinburgh to develop a smartphone app that could help diagnose delirium
- Research into a new device that could help to relieve the pain and discomfort experienced by thousands of amputees as a result of poorly-fitting replacement lower limbs. The sensors for the device, invented by Dr Liudi Jiang and colleagues at the University of Southampton, measure the pressure and pulling forces at the interface between a patient's stump and the socket of their prosthesis
- A team of scientists at the University of Essex has been awarded Biomedical Catalyst funding to develop an artificial blood substitute with a shelf life of up to two years. The work is co-funded by the Biotechnology and Biological Sciences Research Council
- OxSonics is developing ultrasound-based medical devices including SonoTran, that can deliver drugs throughout tumours including difficult to reach areas such as those that lie farthest from blood vessels.



# Lifestyle changes that could fend off dementia

*A poll has shown that more than a fifth of UK people do not think it is possible to reduce their risk of developing dementia.*

The findings in the YouGov poll commissioned by the Alzheimer's Society come despite evidence that lifestyle factors can improve the chance of avoiding dementia.

The poll found that 22% of the general public are unaware of the benefits of lifestyle changes.

The Alzheimer's Society recommends the following five simple things you can start doing now to reduce your risk of developing the condition:

- There's evidence that regular exercise will prevent dementia than for any other measure we might take. Walking regularly is an excellent way of keeping active
- Eat plenty of fruit and vegetables, fish, olive oil and nuts, a little red wine and not much meat or dairy
- Other conditions like type 2 diabetes and high blood pressure both increase your risk of developing dementia, so get these checked and follow medical advice to keep them under control
- Avoid smoking - it significantly increases your risk of developing dementia, most likely because it damages blood vessels and reduces the amount of blood that reaches your brain
- Scientists believe that frequently challenging your brain with new things is the key, for example taking up a new hobby, learning a language or walking an unfamiliar route.

Dr Clare Walton, from the Alzheimer's Society, said: "800,000 people in the UK have a form of dementia but with no cure yet, we need a significant public health effort to attempt to reduce the number of future cases of the condition."

"We know that what is good for your heart is good for your head and there are

simple things you can start doing now to reduce your risk of developing dementia. Regular exercise is a good place to start as well as avoiding smoking and eating a Mediterranean diet.

"It is never too early to start making healthier choices that could help your memory - whether that's hitting the gym or just walking instead of catching the bus, it all helps." Ruth Langsford, Alzheimer's Society Ambassador and presenter of ITV's This Morning and Loose Women, said: "My wonderful dad had dementia, so naturally I have concerns that I might get it too."

"Like a worrying number of us, I didn't realise until recently that there are simple things you can do to reduce your risk, such as exercising regularly. Now I try to eat healthily, keep active and go on long walks with our dog, Maggie."

\* Obesity in mid-life is linked to a heightened risk of dementia in later life, according to researchers at the University of Oxford.

They also found that the age at which a person is obese seems to be a key factor with an apparent tripling in the risk of developing dementia for people who are obese in their thirties.

The increased risk of dementia declined as obesity was diagnosed later in life, and those who were obese over the age of 70 were not more likely to develop dementia than those without obesity.



## New fellowships

Action Medical Research, which funds research to help sick and disabled children, is financing three new fellowships:

- Dr J R Cook, Imperial College London, £156,036, to produce a test to identify women at risk of preterm labour
- Dr S Bailey, University of Cambridge, £197,895 to study inhibitors of microRNAs in malignant germ cell tumours
- Dr M F Griffin, University College London, £199,970 to develop ear implants for children using a unique synthetic polymer.

## Funding announced for healthcare projects

The UK-based Technology Strategy Board (TSB) has published its 2014-15 plan, which includes a £400m investment in new competitions designed to fund innovative ideas. A total of £80 million has been set aside for programmes in the healthcare sector.



## Living with cancer

A team of cancer survivors in Glasgow have graduated to become Scotland's first fully trained Macmillan Supporters.

The new Macmillan Supporters, who are all volunteers, have either had a personal cancer experience or cared for someone with cancer.

Each of the volunteers completed comprehensive training, which has been quality assured by Queen Margaret University, Edinburgh.

The new initiative from Macmillan Cancer Support is being delivered in partnership with NHS Greater Glasgow & Clyde.



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# Agreement offers hope for lung cancer patients

*An agreement has been signed to develop technology which can treat lung cancer.*

Cancer Research UK and Cancer Research Technology (CRT), the charity's development and commercialisation arm, have reached an agreement with Asterias Biotherapeutics, Inc., a biotechnology company.

Asterias works in regenerative medicine and the agreement will see it advance its novel immunotherapy treatment AST-VAC2 into clinical trials in subjects with non-small cell lung cancer.

AST-VAC2 represents the tenth treatment to enter Cancer Research UK's Clinical Development Partnerships scheme, with six having progressed into the clinic.

A non-patient specific (allogeneic) cancer vaccine, AST-VAC2 is designed to stimulate patients' immune systems to attack telomerase, a protein that is expressed in more than 95% of cancers but is rarely expressed in normal adult cells.

The vaccine was developed following successful early phase clinical trials of a similar, patient specific (autologous) Asterias vaccine, called AST-VAC1, which was derived from patients' blood cells and tested in prostate cancer and acute myeloid leukemia.

Unlike AST-VAC1, and other patient specific vaccines that are developed from a patient's own cells, AST-VAC2 is derived from human embryonic stem cells.

This means that it can be produced on a large scale and stored ready for use, rather than having to produce a specific version of the drug for each patient.

Pedro Lichtinger, Asterias' chief executive officer, said: "The Asterias collaboration with Cancer Research UK's Drug Development Office and CRT represents a major step in advancing our proprietary dendritic cell platform for the potential benefit of patients.

"AST-VAC2 is based on a specific mode of action that is complementary and potentially synergistic to other immune therapies. We are delighted to partner with Cancer Research UK to advance this important platform through Phase 1/2 clinical trials.

"Cancer Research UK's Drug Development Office has the global recognition of having the quality, capability and track record of successfully advancing development programmes.

"We are excited about the possibility of favorably impacting the lives of patients across multiple cancers and are proud to be working with Cancer Research UK."

Under the agreement, Asterias will complete development of the manufacturing process for AST-VAC2. Cancer Research UK will then produce the vaccine and conduct the phase 1/2 clinical trial in the UK.

On completion of the clinical trial, Asterias will have an exclusive first option to acquire a license to the data from the trial on pre-agreed terms including an upfront payment, milestones and royalties on sales of products.

If Asterias declines this option, CRT will then have an option to obtain a license to

Asterias' intellectual property to continue the development and commercialisation of AST-VAC2 and related products in exchange for a revenue share to Asterias of development and partnering proceeds.

Dr Jane Lebkowski, president of research and development at Asterias, said: "The use of human embryonic stem cells to derive allogeneic dendritic cells for cancer immunotherapy has the potential to dramatically improve the scalability, consistency, and feasibility of cellular cancer vaccines.

"We believe this collaboration will enable the acceleration of clinical studies of AST-VAC2 and the collection of important proof-of-concept data for the entire human embryonic stem cell-derived dendritic cell immunotherapy platform."

Nigel Blackburn, Cancer Research UK's Director of Drug Development, said: "Recent advances in cancer immunotherapy have demonstrated the exciting potential of these treatments to improve outcomes in devastating diseases such as lung cancer. Better treatment options for lung cancer are badly needed and it is through collaborations such as this that we can save more lives sooner."

## Supporting engagement

The Wellcome Trust has announced three new Engagement Fellows. Now in its fourth year, the scheme supports people involved with science communication.

Alex Julyan, an artist, will look at healthcare environments as potential places of wellbeing.

Brian Lobel's work will include touring his exhibition Fun with Cancer Patients which reflects on the experiences of teenagers with cancer.

Dan Bird, Exhibitions Director of At-Bristol, will be working in consultation with a network of science centres to understand how people learn.

## Deal is signed

Teesside-based research peptide manufacturer Cambridge Research Biochemicals has signed a non-exclusive license with The Scripps Research Institute (TSRI) to add the click labelling of peptides and proteins, to its existing portfolio.

CRB provides complex and heavily modified peptides to researchers within the Life Sciences discipline.

The partnership with TSRI will enable the company to synthesise more creative and complex peptide targets utilising click chemistry, particularly those considered to be of high importance in drug discovery.

## Researchers sniff out a solution

Scientists have devised an electronic-nose which can sniff the highly infectious bacteria C-diff, which causes diarrhoea, temperature and stomach cramps.

The team at the University of Leicester used a mass spectrometer to demonstrate that it is possible to identify the unique 'smell' of C-diff, which would lead to rapid diagnosis.

They say that it could be possible to identify different strains of the disease simply from their smell, effectively a chemical fingerprint.





## Fund supports charities' access to research

An alliance of leading UK medical research charities has launched a fund to help make charitably-funded research freely available as soon as it is published.

Arthritis Research UK, Breast Cancer Campaign, the British Heart Foundation, Cancer Research UK, Leukaemia & Lymphoma Research, and the Wellcome Trust have joined together to create the Charity Open Access Fund (COAF).

COAF is a two-year pilot and will collect £12 million into a single pot of money available to researchers who are funded by any of the charities and based at any of 36 universities and research institutes covered by the scheme.

Researchers can apply through their universities to access the fund, which will pay the article processing charge to make their work freely available as soon as it is published.

Greg Clark, Minister of Universities, Science and Cities, said: "Opening up access to the latest medical research will bring real benefits to researchers, patients and society. The Government is committed to ensure the widest possible access to research to develop new treatments quicker and the announcements by the UK's leading medical charities will help to achieve this."

The six partners are members of the Association of Medical Research Charities (AMRC), which played a key role in the establishment of the partnership.

AMRC Chair, Lord Willis of Knaresborough, said: "The Charity Open Access Fund is a fantastic example of medical charities working together to ensure their research has maximum impact. We are confident that this pilot is the first step on a journey to a system where research findings are more freely available. We hope the COAF will lead to even more exciting breakthroughs in the understanding, treatment and diagnosis of disease."

# Step forward in asthma management

*More than half of the GP surgeries in the UK are being given a tool that enables them to manage their asthma more effectively*

Asthma UK worked with EMIS, the UK leader in clinical IT systems for GPs and commissioners to develop the new tool, a personalised electronic Asthma UK action plan.

The plan can be printed out in the practice and given, or emailed, to the patient and an electronic version saved on the patient's notes.

Kay Boycott, Chief Executive of Asthma UK, said: "Nobody with asthma should leave their GP surgery without an asthma action plan.

"Research shows you're four times more likely to end up in hospital without one - yet shockingly, only 22% of people with asthma have an action plan.

"This new system will change that by ensuring that GPs and nurses can generate one directly through the EMIS system itself – and it can't come soon enough. This is a no cost, practical solution to save time in appointments as well as proving better care for people with asthma.

"Using an Asthma UK action plan as part of an asthma review gives patients the critical information they need to manage their condition effectively. In the UK today, every ten seconds someone has a potentially life threatening asthma attack and still three people die every day.

"Tragically, the majority of these could be prevented with the right basic care. Our ultimate aim is to make the NHS asthma review the most effective in the world at preventing potentially life threatening asthma attacks."

Asthma UK hopes to work with other software providers to make the tool available to all GPs and practice nurses across the UK.



*This new system will change that by ensuring that GPs and nurses can generate one directly through the EMIS system itself – and it can't come soon enough.*

*Kay Boycott*  
Chief Executive of Asthma UK





# Never lose a sample again - Extremely durable lab identification labels from Brady -

Brady Corporation R&D teams have developed extremely durable and printable identification labels for laboratory samples. "These labels have been engineered to stay attached to samples even when frozen with liquid nitrogen or heated in an autoclave. The ink used to print them can resist chemicals typically used in laboratories to ensure their legibility and to avoid sample loss", says Tugba Sert, EMEA Product Manager at Brady.

## SAMPLE IDENTIFICATION CHALLENGES

Identifying samples for life in laboratories is not easy. "Samples are stored at  $-196^{\circ}\text{C}$ , they are heated in autoclaves and any laboratory has a number of chemicals present that could easily damage any regular label and render it illegible. When they can no longer be identified, samples become unusable for further scientific research. The average cost of losing one sample has been calculated, in a clinical lab setting, at 550 euro. With all of the above arguments in mind, Brady scientists and engineers successfully set out to discover new label constructions to ensure sample traceability for life."



## IDENTIFIABLE FOR LIFE

"Brady laboratory label materials resist the challenging conditions in laboratories, and can withstand a range of chemicals commonly used in laboratories. Using its specifically developed lab label constructions, Brady then created user friendly label formats to easily identify vials, tubes, slides, straws and tissue cassettes. In the right conditions, these engineered label constructions can even be applied to already frozen samples."

"Next to sample labels, Brady also supplies easy to use printing systems with label wizards and built-in symbol libraries enabling scientists to accurately and swiftly label

any sample. The printers barcode capability ensures that all necessary information can be attached to the sample itself, on a label that stays in place and saves researchers from a potentially sticky situation."

## SAMPLE CERTAINTY WHITE PAPER

Brady researchers have created a white paper explaining their point of view and outlining any governmental and regulatory requirements regarding sample traceability. Also available are technical data sheets on Brady's laboratory labels showing results from all tests conducted. Contact Brady at [emea\\_request@bradycorp.com](mailto:emea_request@bradycorp.com) for the white paper 'Sample Certainty' or for technical data sheets on Brady's laboratory labels.



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## Insight into the human body clock

A team of researchers have come up with new findings into the body clock, which could change the way we treat sleep disorders.

Researchers have shown for the first time that brain cells do not all follow the same 24-hour cycle, but can vary in their routines.

Dr Ezio Rosato and Professor Bambos Kyriacou at the University of Leicester have shown that, at least in flies, brain cells called neurons tend to cycle with different periods, and only when they synchronise together do they produce the 24 hour rhythms that they recognise.

They observed that some cells have a tendency to follow a longer than 24 hour rhythm, whereas others work on a slower cycle.

Dr Ezio Rosato, senior author of the paper, said: "Although the day is always 24 hour, the light cycle changes with seasons and our biological functions adapt to it.

"A multiple speed clock allows us to go faster and then slow down to accommodate those changes, but staying within the 24 hour limit of a day.

"For instance, in summer we prefer to get up earlier and to go to bed later than in winter. That requires speeding up and then slowing down the same function during the day."

The study was funded by the Biotechnology and Biological Sciences Research Council (BBSRC).

Professor Melanie Welham, Director of Science at BBSRC, said "There is very clear evidence that disruption of our body clocks has real and negative consequences for our health. This new insight into the way fruit flies' body clocks work gives us a potential new avenue for finding approaches to treating sleep disorders, for example."

Dr Rosato said: "It is likely that future studies will reveal a similar organisation for the body clock of humans.

"Our clock can be desynchronised by many influences, such as shift work, transcontinental travel, ageing, or disease. This knowledge could help alleviating the symptoms of a broken clock because we could treat the neurons, for which many drugs exist, rather than specifically treating the clock, resulting in improved quality of life."

## Epilepsy work could throw light on the human condition

New research from the Royal Veterinary College canine epilepsy clinic has provided information on why some dogs do not respond to anti-epilepsy treatments.

The work could shed light on the condition in humans due to similarities between the condition in man and dog.

Epilepsy is the most common chronic neurological condition found in dogs and humans and past studies have found that in a third of dogs, drug treatments failed to reduce the number of seizures they experience by 50 per cent.

The latest study sought to find out why some dogs respond well to treatment, and become seizure-free, while others continue to have seizures over a long period.

Researchers analysed data from six years of medical history taken from the epilepsy clinic at the RVC's Small Animal Referral Hospital.

The results show that seizure density, how close together seizures occur, rather than the number of seizures is a more telling sign of achieving remission in canine epilepsy. Similar results have previously been found in human epilepsy.

The researchers say that further research into the drug treatments in dogs could also improve understanding of the disorder in human beings.

Traditionally in human medicine, epilepsy patients are treated with AEDs (Anti Epilepsy Drugs) immediately after the onset of the condition.

The study found that time to treatment after diagnosis, or the number of seizures experienced before treatment, did not affect the likelihood of achieving remission.

The sex of the dog was also found to be an important risk factor with male animals less likely to go into remission than female dogs receiving AED treatments.

Border Collies and German Shepherds are at a significantly higher risk of not responding to anti-epileptic drugs than other breeds, according to the research.

Prof Holger Volk, Clinical Director of the RVC's small animal referral clinic and specialist in Neurology and Neurosurgery said: "Canine epilepsy is a complex condition and can be very distressing for the dog and their owner.

"Drug treatments can be successful in reducing seizures but it is important to note that consistent remission is difficult to attain."

Co-author of the study and Clinical Investigations Research Assistant at RVC, Dr Rowena Packer, said "In its worst form canine epilepsy can be life threatening to dogs, but it is a dog's long term quality of life that is most affected.

"It can also take a toll on the owners who have to manage this unpredictable, uncontrollable condition.

"Therefore it is important manage owners' expectations with regards to drug treatments. Studies like this are important and can have wider implications for the treatment of epilepsy in humans as well as dogs."

The Royal Veterinary College (RVC) is the England's largest and longest established veterinary school and is a College of the University of London.



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# Undiagnosed + untreated = an entirely new approach needed to tackle a growing burden of liver disease

Dr Simon Goldman and  
Dr Wendy Alderton

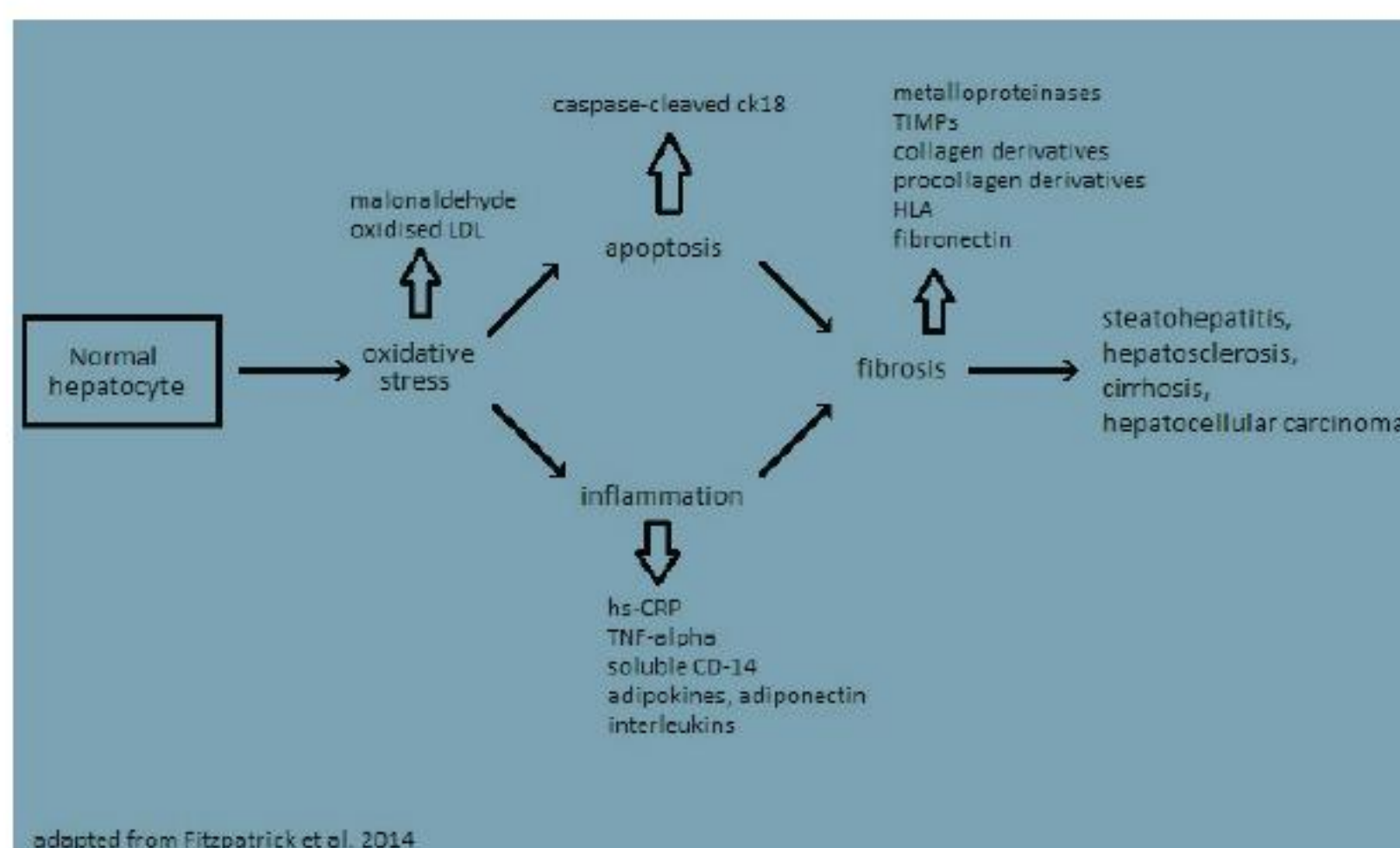
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The healthcare 'maths' of liver-disease diagnosis and treatment simply doesn't add up, not only in terms of the large and increasing cost to healthcare systems globally, but also – and far more importantly – from the perspective of poor individual health outcomes. And the main factor in the equation is the failure of the current diagnostic paradigm to detect disease before it's too late.

Chronic liver disease is one of the leading causes of human mortality globally, resulting in almost two million deaths per annum, due largely to lifestyle factors in developed economies (metabolic disease, alcohol consumption), and from viral hepatitis in emerging markets (World Health Organization, Global Burden of Disease 2010). Recent estimates suggest that as many as 50% of the adult population in some Western countries have undiagnosed non-alcoholic fatty liver disease (NAFLD), which is the precursor to more serious chronic liver disease (see Figure). Yet this cluster of diseases remains significantly under-addressed in global healthcare responses, resulting in one of the largest sources of preventable death in the world.

The most significant hurdle is that the 'gold-standard' for diagnosis of liver-related disorders is a surgical procedure – liver biopsy and histopathology. While this enables clinicians to identify other liver injuries – such as inflammation, steatosis or necrosis – it is not only invasive, painful and expensive, but it is often inaccurate due to sampling errors (e.g. clinician taking tissue from a non-diseased section of liver) and there is significant variability in interpretation of pathology results. Widespread use of an invasive surgical procedure to screen for disease is, obviously, infeasible – and this is particularly problematic as the early stages of liver disease are often asymptomatic, and disease diagnosed at a late stage is much harder to treat successfully.

A number of non-invasive tests for liver disease are available, but none has yet to supplant biopsy for confirmatory diagnosis. So-called 'liver-function' tests based on blood



biomarkers such as liver transaminases, albumin and bilirubin are widely used, but show generally poor performance: a recent community-based, prospective study of patients with abnormal liver-function results established diagnosis in fewer than 5% of cases (Lilford et al., 2013).

In general, biomarkers that perform well as diagnostic tests are those that closely reflect underlying pathophysiology and can reveal disease staging and progression so that differential clinical decisions can be made. In this regard, the key factors in diagnosis of liver disease are determining the degree and rate of progression of liver fibrosis, although markers of inflammation and necrosis do provide distinct information (see Figure). Novel imaging methods such as transient elastography are useful for detecting fibrosis, but do not provide information on the underlying disease processes. A significant focus of discussion at the International Liver Convention in London this past April was around ways in which such imaging methods could be combined with new (more relevant) blood-based biomarker tests/panels to provide more sensitive diagnosis.

However, despite many of these newer tests providing improved information, they remain reliable only for late-stage diagnosis, and determination of progression is simplistic and can result in errors of diagnosis (both

false-positives and negatives). This is because, currently, tests compare biomarker levels for different stages of liver fibrosis using pre-determined cut-offs based on population averages to separate the stages. However, some people may show different biomarker levels simply because of natural healthy variation and might therefore be diagnosed incorrectly. Further, repeat testing over time and 'recategorisation' on the basis of changes in biomarker levels is ad hoc and remains prone to miscategorisation for the precisely same reason – the cut-offs are not personalised.

And this is where the mathematics of diagnosis comes in to its own: measuring biomarkers in individuals at regular intervals when healthy (serial screening) enables personalisation of a diagnostic by spotting changes in a marker relative to their own baseline, rather than in comparison to other people's levels. Quantitative algorithms can be used to identify even small biomarker changes, enabling a far more powerful method of diagnosis (increased sensitivity/specificity), meaning that relevant changes can be picked up far earlier in disease progression, and enabling intervention and improved healthcare outcomes.

October is Liver Awareness Month.



# Enzyme research offers hope for stroke patients

*Research has identified that a drug that blocks the action of the enzyme Cdk5 could substantially reduce brain damage if administered shortly after a stroke.*

The research by a team at the UT Southwestern Medical Center in America showed that aberrant Cdk5 activity causes nerve cell death during stroke in rodents.

Dr. James Bibb, Associate Professor of Psychiatry and Neurology and Neurotherapeutics at UT Southwestern and senior author of the study, said: "If you inhibit Cdk5, then the vast majority of brain tissue stays alive without oxygen for up to one hour. This result tells us that Cdk5 is a central player in nerve cell death."

The team say that development of a Cdk5 inhibitor as an acute neuroprotective therapy has the potential to reduce stroke injury.

Dr Bibb said: "If we could block Cdk5 in patients who have just suffered a stroke, we may be able to reduce the number of patients in our hospitals who become disabled or die from stroke. Doing so would have a major impact on health care."

Several pharmaceutical companies worked to develop Cdk5 inhibitors years ago, but the team says the efforts were largely abandoned since research indicated blocking Cdk5 long-term could have detrimental effects.

At the time, many scientists thought aberrant Cdk5 activity played a major role in the development of Alzheimer's disease and that Cdk5 inhibition might be beneficial as a treatment.



**Dr. James Bibb**

Associate Professor of Psychiatry and Neurology and Neurotherapeutics at UT Southwestern

Based on Dr. Bibb's research and that of others, Cdk5 has both good and bad effects. When working normally, it adds phosphates to other

proteins that are important to healthy brain function.

However, researchers have found that aberrant Cdk5 activity contributes to nerve cell death following brain injury and can lead to cancer.

Dr Bibb said: "Cdk5 regulates communication between nerve cells and is essential for proper brain function. Therefore, blocking Cdk5 long-term may not be beneficial."

"Until now, the connection between Cdk5 and stroke injury was unknown, as was the potential benefit of acute Cdk5 inhibition as a therapy."

Researchers administered a Cdk5 inhibitor directly into dissected brain slices after adult rodents suffered a stroke, in addition to measuring the post-stroke effects in Cdk5 knockout mice.

Dr Bibb said: "We are not yet at a point where this new treatment can be given for stroke. Nevertheless, this research brings us a step closer to developing the right kinds of drugs."

"We first need to know what mechanisms underlie the disease before targeted treatments can be developed that will be effective. As no Cdk5 blocker exists that works in a pill form, the next step will be to develop a systemic drug that could be used to confirm the study's results and lead to a clinical trial at later stages."

## Team answers questions about the brain

Scientists in America are throwing new light on the way the brain works. Researchers at the National Institutes of Health took a molecular-level journey into microtubules, the hollow cylinders inside brain cells that act as skeletons and internal highways.

During the process, they saw how the protein tubulin acetyltransferase (TAT) labels the inside of microtubules, which offers new information on TAT's role in brain health.

The scientists say that microtubules are tagged by proteins in the cell to designate them for specialised functions, in the same way that roads are labelled for fast or slow traffic.

Recent findings suggested that problems with tagging microtubules may lead to

some forms of cancer and nervous system disorders, including Alzheimer's disease, and have been linked to a rare blinding disorder and Joubert Syndrome, an uncommon brain development disorder.

Antonina Roll-Mecak, Ph.D., an investigator at the NIH's National Institute of Neurological Disorders and Stroke (NINDS), Bethesda, Maryland, and the leader of the study, said: "This is the first time anyone has been able to peer inside microtubules and catch TAT in action. Our study uncovers how TAT may help cells distinguish between stable microtubules and ones that are under construction."

For decades scientists knew that the insides of long-lived microtubules were often tagged with acetyl groups by TAT.

Changes in acetylation may influence the health of nerve cells. Some studies have shown that blocking this form of microtubule tagging leads to nerve defects, brain abnormalities or degeneration of nerve fibres.

Further studies may help researchers understand how microtubule tagging influences nerve cells in health and disease.

This work was supported by the NINDS Intramural Research Program, the NHLBI Division of Intramural Research and the Howard Hughes Medical Institute.



## Food for thought

A better understanding of the genes involved in taste perception and food preferences could lead to personalised nutrition plans which could aid weight loss and avoid diseases such as cancer, depression, and hypertension, Italian researchers say.

Dr Nicola Pirastu and Dr Antonietta Robino, from the University of Trieste and the IRCCS Burlo Garofolo Institute for Maternal and Child Health, Trieste, Italy,

reported their findings to the annual conference of the European Society of Human Genetics.

## Agreement is next step in sequencing

Pacific Biosciences of California, and Dutch company GenDx, a pioneer in the area of sequence-based typing, have announced a co-marketing agreement to offer products for full-length HLA gene sequencing.

The Human Leukocyte Antigen (HLA) system consists of a large family of highly variable genes and allelic variants that forms the basis of the human immune system. High-resolution HLA typing and sequencing plays a key role in autoimmune disease-association studies, drug hypersensitivity research and other applications.

## Improve dementia care, says study

A new study says that American policymakers should consider more ways to improve support for the rising number of people with dementia.

The RAND Corporation estimates that 15 per cent of Americans older than 70 suffer from dementia-related conditions.

Lead author Regina A. Shih, a senior behavioural scientist, said: "As baby boomers reach the ages of highest dementia risk, the nation faces urgency in finding ways to improve long-term services and supports specifically for this condition."



# Strokes linked to Alzheimers, say researchers

Research conducted by the Department of Medicine and Therapeutics at The Chinese University of Hong Kong (CUHK) has shown a strong link between strokes and Alzheimer's Disease.

The work reveals that cerebrovascular diseases (stroke) are closely correlated with Alzheimer's dementia.

That means that patients with underlying Alzheimer's dementia pathology have a 90% chance of developing dementia after a stroke.

However, the findings also suggest that improving vascular health can prevent or delay the onset of Alzheimer's dementia.

Alzheimer's dementia is the most common neurodegenerative disease worldwide with more than 35 million people, including 70,000 in Hong Kong, suffering from the disease.

Traditionally, Alzheimer's dementia and cerebrovascular disease have been regarded as different diseases.

That has been challenged by a research team led by Prof. Vincent C.T. Mok, Division of Neurology, Department of Medicine and Therapeutics at CUHK.

They studied 1,013 Chinese people with an average age of 70 years who suffered from mild to moderate strokes in 2009 and 2010.

The result showed that among those who were found to harbour amyloid plaques in their brains, 90% developed dementia after a stroke.

Professor Mok said: "From the emergence of amyloid plaques in the brain, it takes 10 to 15 years more on average for the patient to develop dementia.

"However, a very minor stroke, or even a transient ischemic attack, is able to trigger dementia onset in patients with underlying amyloid plaques. In other words, a stroke is a catalyst of the process.

"Early studies recognized that cerebrovascular disease is present in as many as 50% of Alzheimer's dementia patients. Therefore, we believe that 50% of dementia can be prevented or delayed if cerebrovascular disease can be prevented, despite the lack of effective treatment towards amyloid plaques."

Dr Lisa Au, Clinical Tutor (Honorary), Division of Neurology, Department of Medicine and Therapeutics at CUHK, said: "The present study provides strong evidence that cerebrovascular disease triggers Alzheimer's dementia. Maintaining vascular health will not only lower the risk of cardiovascular and cerebrovascular disease, but also prevent dementia."

Dr Au said that preventive measures for cerebrovascular disease could help, including treatment of hypertension and dyslipidemia, stopping smoking, more physical activity, losing weight in the obese, a healthy diet and the use of anticoagulant drugs in subjects with atrial fibrillation.

The research team will now further investigate the pathology of Alzheimer's dementia including estimating the prevalence of amyloid plaques among dementia-free elderly subjects and exploring whether or not certain drugs are able to clear up amyloid plaques or prevent dementia onset among those with amyloid plaques.



# Scientists investigate links between vasectomies and cancer

*Research conducted in America has suggested that vasectomy is associated with a small increased risk of prostate cancer and a stronger risk of an advanced or lethal type of the illness.*

Researchers from Harvard School of Public Health (HSPH) found that the association remained even among men who received regular screening, suggesting that the increased risk of lethal cancer in the findings cannot be explained by a bias in diagnosis.

It is the largest and most comprehensive study to date to look at the link between vasectomy and prostate cancer.

Co-author Lorelei Mucci, associate professor of epidemiology at HSPH, said: "This study follows our initial publication on vasectomy and prostate cancer in 1993, with 19 additional years of follow-up and tenfold greater number of cases.

"The results support the hypothesis that vasectomy is associated with an increased risk of advanced or lethal prostate cancer,"

Vasectomy is a common form of contraception in the U.S., with about 15% of men undergoing the procedure. Prostate cancer is the second-leading cause of cancer death among US men.

The researchers analysed data from 49,405 U.S. men in the Health Professionals Follow-up



Study, who were followed for up to 24 years from 1986 to 2010.

During that time, 6,023 cases of prostate cancer were diagnosed, including 811 lethal cases. One in four of the men in this study reported having a vasectomy.

The results showed a 10% increased risk of prostate cancer overall in men who had a vasectomy.

Vasectomy was not significantly associated with risk of low-grade cancer but it was associated with a stronger risk of advanced and lethal prostate cancer, with an increased risk of 20% and 19% respectively.

Among men who received regular screening, the increase in risk of lethal prostate cancer was 56% with the effect stronger among men who had a vasectomy at a younger age.

The researchers have emphasised that men considering vasectomies should think about the potential ramifications very carefully before deciding to go ahead.

Co-author Kathryn Wilson, research associate in the Department of Epidemiology at HSPH said: "The decision to opt for a vasectomy as a form of birth control is a highly personal one and a man should discuss the risks and benefits with his physician."

## Slowing condition's progress

Gilead Sciences, has announced updated interim results of a study into a drug that could delay relapses in leukaemia patients.

The Phase 2 study evaluated GS-9973, the company's oral inhibitor of spleen tyrosine kinase, for the treatment of patients with relapsed chronic lymphocytic leukaemia.

In the study, single-agent treatment with GS-9973 achieved an overall response rate of 49 per cent, with an estimated progression-free survival rate at 24 weeks of 70 per cent.

## Award for young scientist

This year's Boehringer Ingelheim FENS Award has gone to Judit Makara from the Institute of Experimental Medicine of the Hungarian Academy of Sciences in Budapest, Hungary.

The biannual 25,000 Euro recognises outstanding research by young scientists in neuroscience and went to Judit for work on the understanding of the mechanisms that determine responses of nerve cells and neuronal circuits when their internal and external environments change.

## China and UK sign research deals

The governments of the UK and China have agreed more than £50 million of joint research programmes to tackle global issues including human diseases, climate change and renewable energy.

They approved programmes worth £53 million and a wider five-year plan which will eventually include deals worth £200 million.

The programmes include joint research partnerships – led in the UK by Research Councils UK – to support advances in regenerative medicine, stem cells and human health.



## Study casts new light on effect of hormone

Twenty years after the hormone leptin was found to regulate metabolism, appetite, and weight through brain cells called neurons, Yale School of Medicine researchers in America have found that it also acts on other types of cells to control appetite.

The findings could lead to development of treatments for metabolic disorders such as obesity and diabetes.

Senior author Tamas Horvath, the Jean and David W. Wallace Professor of Biomedical Research and chair of comparative medicine at Yale School of Medicine, said: "Up until now, the scientific community thought that leptin acts exclusively in neurons to modulate behaviour and body weight."

Leptin, a naturally occurring hormone, is known for its hunger-blocking effect on the hypothalamus in the brain. Food intake is influenced by signals that travel from the body to the brain.

Leptin is one of the molecules that signal the brain to modulate food intake. It is produced in fat cells and informs the brain of the metabolic state. If animals are missing leptin, or the leptin receptor, they eat too much and become severely obese.

Leptin's effect on metabolism has been found to control the brain's neuronal circuits, but no previous studies have definitively found that leptin could control the behaviour of cells other than neurons.

The team knocked out leptin receptors in the adult non-neuronal glial cells of mice and recorded the water and food intake, as well as physical activity. They found that animals responded less to feeding reducing effects of leptin but had heightened feeding responses to the hunger hormone ghrelin.

## Development could improve brain cancer treatment

*Scientists have revealed an encouraging development in the understanding of brain cancer.*

The researchers at the University of California, San Diego School of Medicine in the United States have identified a biomarker that predicts whether glioblastoma – the most common form of primary brain cancer – will respond to chemotherapy.

According to the lead investigator, the work will reduce the administration of treatments from which the patient will derive little benefit.

Clark C. Chen, MD, PhD, vice-chairman of Academic Affairs, Division of Neurosurgery, UC San Diego School of Medicine and the study's principal investigator, said: "Every patient diagnosed with glioblastoma is treated with a chemotherapy called temozolomide. About 15 per cent of these patients derive long-lasting benefit.

"We need to identify which patients benefit from temozolomide and which another type of treatment. All therapies involve risk and the possibility of side-effects. Patients should not undergo therapies if there's no likelihood of benefit."

The researchers studied microRNAs that control the expression of a protein called methyl-guanine-methyl-transferase or MGMT, which reduces the cancer-killing effect of temozolomide. Tumours with high levels of MGMT are associated with a poor response to temozolomide therapy.



The scientists tested every microRNA in the human genome to identify those that suppressed MGMT expression.

Clark C. Chen said: "Validation of these results should lead to diagnostic tools to enable us to determine which patients will benefit most from temozolomide therapy."

The team also discovered that injection of the MGMT-regulating microRNAs into glioblastoma cells increased the way tumours respond to temozolomide treatment.

Lead author, Valya Ramakrishnan, PhD, postdoctoral researcher, UC San Diego School of Medicine, said: "These findings establish the foundation for microRNAs-based therapies to increase the efficacy of temozolomide in glioblastoma patients."

Funding for the research came, in part, from the Sontag Foundation, Burroughs Wellcome Foundation, Kimmel Foundation and the Forbeck Foundation.

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# Imaging Services Accreditation Scheme

ISAS is a patient-focussed assessment and accreditation programme that is designed to help diagnostic imaging services ensure that their patients consistently receive high quality services delivered by competent staff working in safe environments.

ISAS is the only nationally recognised accreditation scheme available for diagnostic imaging services in the UK and provides an essential framework for services to engage with a key deliverable outlined in the recently published NHS England business plan:



... ensure that more than 70% of all scientific and diagnostic services are part of accreditation programmes and demonstrate robust quality assurance measures by end of March 2015.”

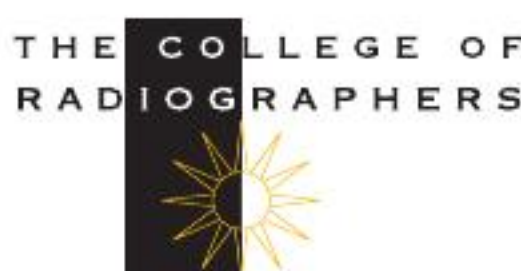
*Putting Patients First – NHS England Business Plan 2014-15 to 2016-17*

If you would like to find out more about ISAS accreditation, please contact UKAS:

[ImagingCustomerService@ukas.com](mailto:ImagingCustomerService@ukas.com)

020 8917 8400

[www.ukas.com](http://www.ukas.com) / [www.isas-uk.org](http://www.isas-uk.org)



UKAS has been appointed by the RCR and CoR to deliver ISAS accreditation.



We strive to provide high quality care to our patients each and every day. Our ISAS award provides additional assurance to everyone using the hospital that they are receiving high quality, safe and effective services.”

**Chief Executive,**  
West Suffolk Hospital NHS Trust



# Accreditation: Delivering Confidence in Health Services

*The quality of health and social care services is under constant and close scrutiny. Professor Sir Mike Richards, Chief Inspector of Hospitals at the Care Quality Commission (CQC) has recently acknowledged that accreditation and peer review processes already play an important part in stimulating and supporting quality improvements.*

The role of UKAS accreditation within the health and social care sector has also recently been formally recognised in a joint policy agreement released by the Department of Health (DH) and Department for Business, Innovation and Skills (BIS).

The DH/BIS policy agreement highlights that "Accreditation increases trust in conformity assessment and thus reinforces the mutual recognition of products, processes, services, systems, persons and bodies across the EU". It goes on to state that where new quality assurance schemes are planned in the NHS or social care, particularly where there is interest in schemes awarding certification or accreditation, their initiators should work with The United Kingdom Accreditation Service (UKAS) from an early stage to ensure that the schemes are sufficiently rigorous to meet EU and UK accreditation requirements.

The drive for accreditation in the health sector is mirrored in the NHSE business plan for 2014-15 to 2016-17. A key deliverable of the plan is to "ensure more than 70% of all scientific and diagnostic services are part of accreditation programmes and demonstrate robust quality assurance measures by end of March 2015."

Whilst this may appear to be an ambitious target, as the UK's National Accreditation Body, UKAS already underpins quality in the delivery of a number of health and social care services. These include pathology, diagnostic imaging (ISAS), point of care testing and physiological services (IQIPS). A pilot scheme for the accreditation of inspections of residential adult social care providers began in July, with the first accreditations due in December 2015.



Sponsored by Professor Sue Hill, Chief Scientific Officer for England at DH, the IQIPS programme was created by the Royal College of Physicians (RCP) with the aim of improving the quality of services, care and safety for patients undergoing physiological science service tests, examinations and procedures. It covers a range of eight physiological diagnostic specialisms including audiology, cardiac physiology, gastrointestinal physiology, neurophysiology, ophthalmic and vision science, respiratory and sleep physiology, urodynamics and vascular science.

Highlighting the benefits of the scheme, Professor Hill said, "IQIPS puts physiological scientific services at the leading edge of continuous quality improvement and quality assurance in the NHS. It provides a mark of quality for commissioners, providers and users of service with patient quality outcomes at its core."

Independent assessment and accreditation is a key part of the IQIPS programme and UKAS has been contracted by RCP to deliver the national assessment and accreditation service for all eight physiological diagnostic specialisms. The first IQIPS accreditation was granted to Action for Deafness for adult hearing services at the beginning of 2013. Since then a further 15 audiology services providers from across the public and private sector have achieved IQIPS accreditation.

UKAS is working closely with the RCP on a plan for the staged roll out of accreditation to each specialism. This year Independent Vascular Services (IVS) Ltd became the UK's first vascular laboratory to gain ISAS accreditation for its range of vascular

ultrasound services. Richard Pole, Operations Director at IVS said: "Achieving this badge of quality is something we are particularly proud of, as it represents independent external recognition and affirmation of our good practices, giving confidence to both patients and health care professionals alike. We have found that becoming accredited has driven up the quality of our services and supports the sharing of good practice. It will also hopefully enhance the awareness of vascular ultrasound as a profession across the UK, and could be used as leverage for change."

For further information on the IQIPS programme please visit [http://ukas.com/Library/Media-Centre/Promotional-Materials/Brochures/IQIPS Brochure.pdf](http://ukas.com/Library/Media-Centre/Promotional-Materials/Brochures/IQIPS%20Brochure.pdf)





# Grants will further research into Fragile-X

*The National Institutes of Health in the United States has awarded more than \$35m over the next five years to support research into Fragile-X- associated disorders.*

Grants have gone to researchers at three Centers for Collaborative Research, who are seeking to develop effective treatments.

Fragile X syndrome, Fragile X-associated tremor/ataxia syndrome and Fragile X-associated primary ovarian insufficiency can cause major health problems.

The disorders result from mutations in a single gene, named FMR1. FMR1 normally makes a protein that helps create and maintain connections among cells in the brain and nervous system.

Changes in the gene can reduce or eliminate the protein, which may result in Fragile X syndrome or other conditions.

Not all people with FMR1 mutations display symptoms of Fragile X-associated disorders but their children are at greater risk of inheriting the disorders.

The Centers for Collaborative Research in Fragile X, which were established in 2000, have already advanced the field of Fragile X research through improved understanding and the grants will further the work.

The National Institute of Mental Health and the National Institute of Neurological Disorders and Stroke are also backing the work and grants were awarded to teams led by the following investigators:

Kimberly M. Huber, Ph.D., University of Texas Southwestern Medical Center, Dallas - many people with Fragile X syndrome are sensitive to sensory stimuli, especially noise. Dr. Huber's team will study brain circuits in mouse models and people to try to determine the causes of heightened sensitivity to sound. This information may lead to more targeted therapies.

Joel D. Richter, Ph.D., University of Massachusetts Medical School, Worcester - in collaboration with Gary J. Bassell, Ph.D. (Emory University, Atlanta) and Eric Klann, Ph.D. (New York University), Dr. Richter's research group will study three molecules that appear to play important underlying roles in Fragile X syndrome.

Stephen T. Warren, Ph.D., Emory University - Dr Warren's team will sequence the genomes of patients with FMR1 gene mutations to identify whether additional genes may affect an individual's likelihood of developing certain health problems associated with FMR1 mutations.



**Child showing Fragile-X genetic symptoms**

Tiina Urv, Ph.D, chair of the NIH Fragile X Syndrome Research Coordinating Group and a programme director at the Eunice Kennedy Shriver National Institute of Child Health and Human Development, said: "Past research has revealed a better understanding of the basic functions of the FMR1 gene and about the risk of transmitting FMR1 gene mutations across generations.

"We're hopeful that continued research into Fragile X and related conditions will spur tangible benefits for many that deal with these disorders.

"Each of these centres is focused on a specific research challenge and has the promise to make a significant impact on the field in the next five years."

## New hope for osteoporosis sufferers

Research carried out in America may offer new hope for sufferers of osteoporosis.

A University of Arkansas for Medical Sciences (UAMS) research team has found that reducing the levels of reactive oxygen chemicals in certain cells can increase bone mass and eventually may lead to new treatments.

The research was led by Maria Almeida, Ph.D., an associate professor and researcher in the UAMS Center for Osteoporosis and Metabolic Bone Diseases.

## Approval granted

American company Meridian Bioscience, Inc., of Cincinnati, Ohio, has received medical device license approval from Health Canada to market two additional assays for use on their illumigene® molecular diagnostic platform.

The addition of illumigene Mycoplasma and illumigene Pertussis means that Meridian continues to expand its position in the Canadian market by providing testing solutions that meet the needs of clinical laboratories. The announcement was made with Somagen Diagnostics.

## Taking out the rubbish

Scientists have uncovered evidence that some nerve cells in the eye pass off their old energy-producing factories to neighbouring support cells to be 'eaten.'

The research was led by Nicholas Marsh-Armstrong, Ph.D., a research scientist at the Kennedy Krieger Institute, and Mark H. Ellisman, Ph.D, a neuroscience professor at the University of California, San Diego.

The findings may cast new light on the roots of glaucoma and have implications for Parkinson's, Alzheimer's, amyotrophic lateral sclerosis and other diseases that involve a buildup of "garbage" in brain cells.





## Dubai on the up

*Biotechnology research in Dubai will take a major step forward in 2015.*

Tecom Investments has announced that the opening of the DuBiotech Headquarters, located in the Al Barsha South area, will happen next year.

The DuBiotech Headquarters comprises two high-rise towers that provide more than half a million square feet of office space, less than 30 minutes from Dubai International Airport.

Completion of the development comes on the back of increasing demand by businesses for space in Dubai's new growth corridor.

DuBiotech and EnPark, members of Tecom Investments, are business parks dedicated to fostering the growth of the life sciences and the alternative energy and environmental industries industry in the region.

The developers of the new site are already experiencing significant demand from businesses wishing to establish themselves in one of the fastest growing areas of the Emirate.

Marwan Abdulaziz, Executive Director of Tecom Investments' DuBiotech & EnPark said: "The Headquarters will add further value to the healthcare sector in the region and will help us decrease the reliance on pharmaceutical imports by encouraging R&D and innovation.

"Our new facilities will enable us to continue to provide a platform that fosters a culture of collaboration among peer companies, so that we may achieve our part of the Government's aim to develop a knowledge-based economy." The UAE has the highest annual sales per capita for medicines in the GCC, and the pharmaceutical market in the GCC has witnessed significant growth.

Companies that operate under DuBiotech and EnPark benefit from advantages of being licensed by a free zone, including 100% foreign ownership in a tax-free environment, a guaranteed 50-year exemption from personal, income and corporate taxes, full repatriation of profits and capital, and exemption of custom duty for goods and services

## Young medical researcher among prize winners

Prizes have been awarded to young researchers working in the United States.

Digital media holding company CPXi and Hofstra University announced the winners of the second annual Hofstra-CPXi Venture Tech Challenge, a contest designed to honour young visionaries.

First prize of \$50,000 went to computer science majors Brian Blanco and sophomore Ashish Pandhi for a blog management platform but second place went to a medical researcher.

The \$20,000 was awarded to Justin Phillip Henneman, a fourth year medical student at Hofstra, who designed a solution that lowers the failure rate of ventriculoperitoneal shunts and warns users when they are about to fail.

Fourth-year medical student Justin, who has an MA in mechanical engineering from the University of Hawaii, has been working with North Shore-LIJ's Department of Neurosurgery resident Alexander Gamble, MD, who provided clinical input.

Justin said: "Medical devices take about five to ten years to come to market. The funds will help me to obtain the equipment I need to start building a prototype and a physiological modelled system."

Among the runners-up were fifth placed Anthony Argutto, Nickolas Boroda and Henry Gross for LogCallMD, a communication platform that documents and tracks all doctor-to-doctor and doctor-to-patient communication.

The competition was designed by CPXi founder and CEO Mike Seiman, who graduated from Hofstra with a computer science degree in 2001 and is now a member of the school's Board of Trustees.

Mike said: "We are both thrilled and gratified to be able to offer the opportunity to advance innovative business ideas. Industries can be changed almost overnight by one great idea and a leadership team with the guts to turn that idea into a reality.

"There are no prerequisites for entrepreneurship; all you need is a vision and the courage and work ethic to see it through."

The contest received 40 entries from students across Hofstra University's various majors.

## Honour for US company

American firm Seahorse Bioscience, the world leader in metabolic analysers and assay kits for measuring cell metabolism, has been listed in the 2014 Inc. 5000, the fourth year it has been named.

The list is a ranking of the nation's fastest-growing private companies and 2013 marked Seahorse's fifth year of annual growth averaging 25%.

More than 5,250 scientists worldwide incorporate Seahorse XF Technology in their Research.

## Drug 'still the best

A study says that Levothyroxine should continue to be regarded as 'the gold standard therapy' for an under-active thyroid gland.

The analysis found insufficient data to recommend a change in use of levothyroxine, whether generic or sold under various trade names, as the only drug needed to treat hypothyroidism.

The American Thyroid Association asked lead author Jacqueline Jonklaas, MD, PhD, an associate professor at Georgetown University Medical Center, and ten researchers from three countries to review the existing data.



# Company announces MSA drug research projects

*Drug company Evotec has entered into three novel research projects aimed at coming up with new discoveries for the treatment of Multiple Sclerosis.*

Supported by research funds from the German Federal Ministry of Education and Research, the projects are aimed at bringing new drugs to market.

They have arisen out of work done by the Deutsches RheumaForschungszentrum, an institute of the Leibniz Association, Professor A. Hamann and the University Medical Center Hamburg-Eppendorf.

Evotec will help identify and commercialise drug candidates to tackle MS and the three projects will run for between one and a half and three years and comprise a total budget of about EUR 5m.

Dr Cord Dohrmann, Chief Scientific Officer of Evotec, said: "These novel approaches to fight MS, the disease with the highest socioeconomic impact worldwide, perfectly fit to our EVT Innovate strategy to approach disease-modifying innovation and to identify first-in-class molecules eagerly sought for by the biotech and pharmaceutical industry."

"We are proud to partner with these leading German research institutions and groups to translate their exceptional disease know-how into drug candidates and furthermore into novel products."

Multiple sclerosis is one of the most common diseases of the central nervous system and more than two million people around the world suffer from it.

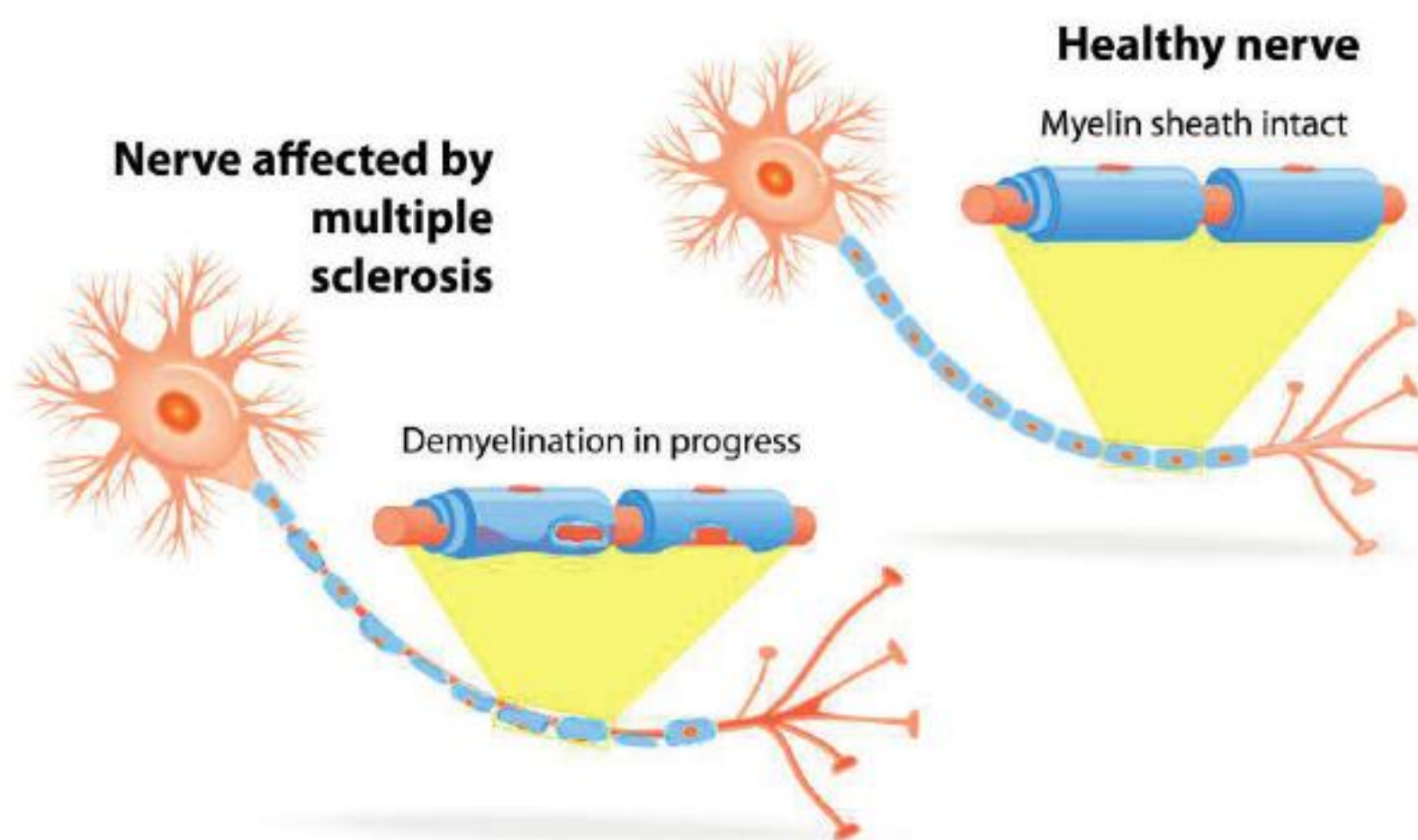
MS is an inflammatory and neurodegenerative disease in which the insulating covers of nerve cells (myelin sheath) in the brain and spinal cord are damaged.

This damage disrupts the ability of parts of the nervous system to communicate, resulting in a wide range of signs and symptoms, including physical, mental, and sometimes psychiatric problems.

MS takes several forms, with new symptoms either occurring in isolated attacks (relapsing forms) or building up over time (progressive forms).

Between attacks, symptoms may disappear completely but permanent neurological problems often occur, especially as the disease advances.

MS is usually diagnosed based on the presenting signs and symptoms and the results of supporting medical tests.



There is no known cure for multiple sclerosis and treatments attempt to improve function after an attack and prevent new attacks.

Evotec is a drug discovery alliance and development partnership company focused on rapidly progressing products products leading pharmaceutical and biotechnology companies.

It has long-term alliances with partners including Bayer, Boehringer Ingelheim, CHDI, Genentech, Janssen Pharmaceuticals, MedImmune/AstraZeneca, Roche and UCB.

\*American company Biogen Idec has announced that five-year results from the ENDORSE Phase 3 extension study show that Tecfidera (dimethyl fumarate) provides strong and efficacy in a broad range of people living with relapsing-remitting multiple sclerosis (RRMS).

The safety profile remained consistent with no new or worsening safety signals across patients in the ENDORSE study who received Tecfidera, including some patients who were treated for up to seven and a half years.

Alfred Sandrock, M.D., Ph.D., group senior vice president and chief medical officer at Biogen Idec, said: "Tecfidera continues to provide patients with effective oral treatment for MS that is supported by a growing body of data reinforcing its benefits and favorable safety profile."

"These new ENDORSE results provide further insight into the positive impact of using Tecfidera early in the course of MS and for long-term treatment of this chronic disease."







# Awards champion role of women

*Two awards have been made to champion the work of women in medicine.*

The American Medical Association's Women Physicians Section and the AMA Foundation have announced the winners of the 2014 Joan F. Giambalvo Fund for the Advancement of Women.

The scholarships, up to \$10,000, are awarded to research programmes focused on identifying and addressing issues affecting women physicians and medical students.

The 2014 recipients are: Elizabeth H. Ellinas, M.D., Associate Professor of Anesthesiology; Assistant Dean of Faculty Affairs; and Chief of Obstetric Anesthesia and Obstetric Anesthesia Fellowship Director at the Medical College of Wisconsin.

Her research topic is Gender Differences in Promotion and Retention: Enhancing the Position of Female Faculty in Higher Academic Rank and Leadership Positions

Sneha Harshad Shah, M.D., Department of Emergency Medicine and Associate Program Director of Emergency Medicine Residency Program at the University of Massachusetts Medical School.

Her research topic is Gender Differences in Empathy and Burnout amongst Emergency Medicine Residents

Robert Wah, M.D., president, American Medical Association, said: "We are proud to recognise two outstanding members of the medical community, whose work is raising awareness about these issues.

"Their work will help propel the AMA's advocacy efforts on the advancement and understanding of women in medicine."



**Left to right: Elizabeth H. Ellinas, M.D and Sneha Harshad Shah, M.D**

The AMA Women Physicians Section (WPS) consists of the more than 70,000 members of the AMA and aims to increase the number and influence of women physicians in leadership roles.

## Panel is launched

Molecular tools specialist Olink Bioscience, of Sweden, has launched Proseek® Multiplex Inflammation, a protein biomarker panel that targets inflammatory diseases.

The company says that the product will be an important tool in the search for multivariate protein expression patterns that could improve prediction and prognosis as well as aiding discovery of new drugs.

Inflammatory mechanisms are involved in diseases where the immune system creates a chronic inflammation, including rheumatoid arthritis, multiple sclerosis, irritable bowel diseases and asthma.

## Programme targets diabetes

The American Medical Association is encouraging St. Petersburg physicians to participate in a pilot programme to help patients prevent type 2 diabetes.

As part of the initiative, physicians screen patients for prediabetes and refer eligible people to the association's Diabetes Prevention Program.

Robert M. Wah, M.D., president of the Association, said: "More than one out of every three American adults has prediabetes and only about 11 per cent are even aware that they are at risk of developing type 2 diabetes."

## Patients enrolled

Norgine has announced the enrolment of the first patient into the US Phase III study for its product NER1006.

The study will evaluate the bowel cleansing efficacy of a two-day split-dosing regimen of NER1006, versus a split-dosing regimen of a trisulfate bowel cleansing solution (SUPREP) in adult patients undergoing colonoscopy.

NER1006 is a polyethylene glycol based bowel preparation that has been developed to provide whole bowel cleansing with an additional focus on the ascending colon.





# Recruiting the right people for medical research

Clinical research is making massive strides in the way we treat illnesses, extending length and quality of life for the patient. Making the breakthroughs possible are medical researchers who rely heavily on the willingness of men and women prepared to take part in research programmes.

Crucial to the work is identifying the right people to take part in trials and one of the companies leading the process is Quintiles, which is using ever-more sophisticated methods to identify the best subjects worldwide.

The company, which was associated with the development or commercialisation of all of the world's top 100 best selling products or compounds in 2013, works across the full range of therapy areas from respiratory and cardiovascular to mental health, oncology, neurology and immunology.

A key part of its work is making people more aware of the massive impact which clinical trials are having on developing new medicines that can reduce death rates or improve quality of life for many conditions including cancer

and heart disease, and also addressing some of the public disquiet about the process.

Quintiles employs more than 950 MDs, 900 PhDs and thousands of clinical educators and medical representatives among its network of 30,000 employees in 100 countries and selecting the right people to take part in research is at the heart of their work.

Senior Director, Health Engagement and Communication, Ruth Slater said: "Recruiting the right people can be a complex process. It is important that we profile the person taking part before they join a research programme to make sure that we have the right person.

"We have to determine what are their physical considerations, are they mentally prepared to go through the process, are they engaged enough to stick with the research. This is in addition to making sure that they are the right age and the right demographic so that we truly represent the community. There are a lot of questions to answer before we decide that they qualify for the research itself.

"A lot of our work is about identifying people early. Much of the clinical work being

undertaken today is focused on prevention and spotting symptoms as early as possible so our work is geared towards identifying and enrolling people who fit into that category.

"That is true, for instance, in neurology research where identifying symptoms in conditions such as Alzheimer's is important. The same is true of the vascular field."

## *Finding the best subjects*

To find the right people and connect them with opportunities to participate in clinical research, the company works in different ways, both digital and on the ground through networks of health organisations at work in communities. One of the most effective methods of connecting patients with research opportunities has been the MediGuard.org site, which is owned and operated by Quintiles. The primary purpose of MediGuard is to promote improved communication directly with patients or healthcare "consumers" to help people understand, and safely use, their medication. By providing up-to-date safety alerts/recalls, along with feedback and reviews from other members, the service is able to



help people make more informed decisions regarding their health.

More than 2.6 million patients in the USA, UK, France, Germany, Spain and Australia have registered from MediGuard, making it one of the largest and fastest-growing health care communities in history and providing a pool of people who have opted-in to be contacted about research opportunities.

Ruth Slater said: "The people who use MediGuard are important because they have already indicated that they wish to learn more about their medication, so are the type of people who might also consider taking part in research. We are able to provide the very latest information on opportunities to take part in upcoming clinical research programmes directly to patients who are of a likely medical profile to be eligible to participate. This is done in a completely anonymous way, which means that patient confidentiality is achieved throughout the recruitment process, thus helping to maintain public confidence in digital recruitment processes.

"We recruit a lot of our subjects through advertising in the digital space. We also acknowledge, however, that there are people out there who do not engage with the digital world but very often they have friends or relatives who do."

To emphasise the potency of digital recruitment, Quintiles points to not just MediGuard.org but also its site ClinicalResearch.com. Recruiting such people in a timely fashion is just one way that Quintiles helps customers to improve their probability of success, through faster and more productive clinical trials.

## Understanding human behaviour key to recruitment

The ultimate aim is to deliver measurable results from data-rich programmes, capturing real-time clinical indicators and patient outcomes which feed into drug development programmes and post-approval safety and real world outcomes monitoring.

The company's experience is drawn from helping to develop or commercialize 100% of the Top 100 best-selling products or compounds of 2013. From 2008 to 2014, Quintiles conducted more than 400 direct-to-patient studies in more than 30 countries and programs in the last 10 years has enrolled more than 9M patients in observational and quality improvement in more than 100 countries with more than 55,000 sites. In addition, it has supported more than 220 product launches in 20 countries since 2009.

One of the key areas on which the company concentrates is behavioural research because understanding the barriers which prevent



people taking part in trials saves time and ensures more effective outcomes.

Despite the many successes regularly reported by research teams, many people remain unconvinced, or unaware, of the importance of clinical trials or indeed of opportunities to participate in clinical research. Quintiles believes that the lack of awareness about medical issues generally is caused by factors including a lack of understanding, poor literacy, and some people's distrust of medicines and doctors.

Meta-analysis of more than 300 different patient surveys, conducted through MediGuard revealed that:

- Fewer than 10% of patients across all therapy areas have ever participated in a clinical trial
- Key reasons for lack of participation are that patients are unaware of clinical trials or have not been asked to participate
- An average of ~72% of patients express an interest in being contacted about local, relevant clinical trials

Ruth Slater said: "Real-world data has become so important and we are working to raise awareness of the importance of research across the world.

"A lot of our work is done in the US where much of the innovation in the field is being carried out and where there is an appreciation of the importance of research but we are working to broaden the opportunities for people both in the US and elsewhere in the world.

"Public understanding of the importance of research differs from country to country, culture to culture and we are working to spread the network and bring in people in the early stages of an illness, which is a key part of that work.

"However, we acknowledge that for some people there is a reluctance, even a fear factor, about taking part in medical research and we are trying to address that. With only one-half of patients who have chronic diseases adhering to treatment recommendations in developed countries<sup>1</sup>, adherence is a major issue."

1. World Health Organization. Adherence to Long-Term Therapies: Evidence for Action. Geneva, Switzerland: WHO; 2003



The result is that patients do not gain the full benefit of their treatment, resulting in a knock-on effect for the healthcare system, which experiences inefficient use of already scarce resources in the short-term and increased long-term costs.

There are consequences for the biopharma industry as well because its innovative products are not used effectively, leading to lower efficacy and diminished perceptions of the value of the product.

But the real impact is human, accounting for about 125,000 lives in America alone and at least 10 per cent of hospitalizations each year, with annual costs to the U.S. healthcare system of \$100 billion to \$289 billion.<sup>2</sup>

In the European Union, non-adherence is estimated to cause 194,500 deaths each year<sup>3</sup>, costing 1.25 billion<sup>5</sup>.

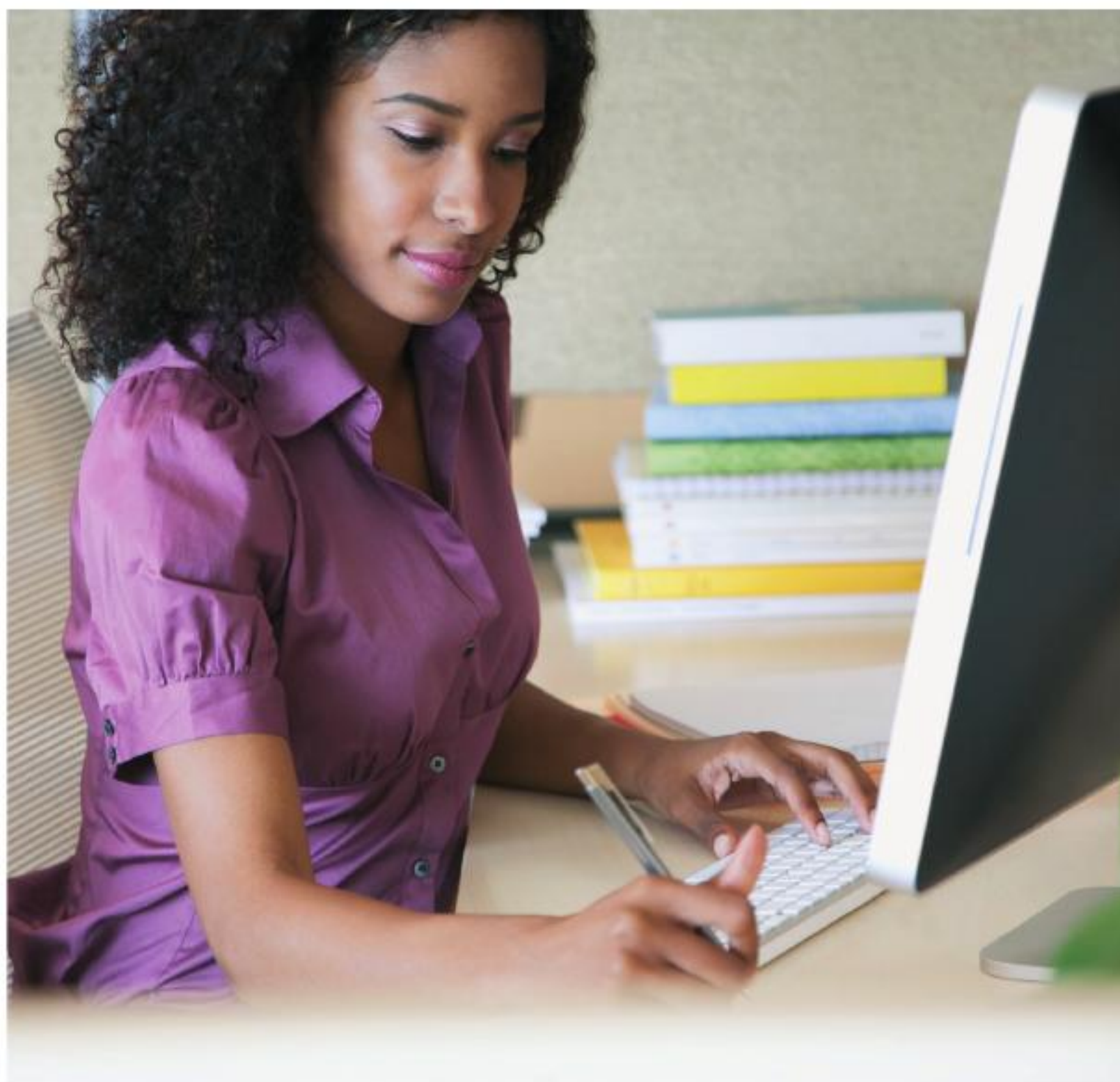
To counteract the lack of awareness, Quintiles supports initiatives which emphasise the success of medical research programme, including International Clinical Trials Day, which takes place every year on May 20, the day that James Lind began the first 'fair test' clinical trial in 1747 into scurvy. Lind is considered the first physician to have conducted a controlled clinical trial of the modern era when, while working as a surgeon on a ship, he became appalled by the high mortality rate for scurvy amongst the sailors.

He conducted a trial of potential treatments, which led to him identifying oranges and lemons because of their high vitamin content although because they were expensive, it was nearly 50 years before the British Navy eventually made lemon juice a compulsory part of the seafarers' diet, and this was soon replaced by lime juice because it was cheaper.

Trials have continued to prove their worth ever since including the first modern clinical trial was conducted by British epidemiologist Austin Bradford Hill who in 1946, conducted a study which identified streptomycin to treat tuberculosis. Their success has also been demonstrated through the impact of new medicines on survival rates in three major diseases.

US cancer deaths declined for the first time since 1930 in the early 2000s, with 369 fewer deaths in 2003 and 3,000 fewer deaths in 2004<sup>4</sup>. Advances in diagnosis, radiation and surgery have all played a part but new drugs have transformed treatment and survival.

Before the first AIDS drug was approved in 1987, HIV/AIDS diagnosis was a virtual death



sentence. HAART (Highly Active Antiretroviral Therapy), introduced in 1996, now makes HIV manageable. In 1993, before HAART, the average life expectancy from diagnosis for Americans with HIV was seven years<sup>5</sup>. Today, a 20-year-old adult who is receiving antiretroviral therapy can expect to live into his or her early 70s.<sup>6</sup>

Broad use of cholesterol-lowering drugs to reduce deaths from coronary heart disease is now recommended by the U.S., Canada, U.K. Europe, Australia and New Zealand. Meta-analysis of 17 clinical trials (21,303 patients) showed a 20% to 30% reduction in death among at-risk patients taking statins.<sup>7</sup>

Ruth Slater said: "We work hard to raise awareness so that people realise that taking part in research can benefit not only themselves but also benefit society. With some people, it's not a case of being unwilling to be involved but rather not being aware of the benefits."



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# Healthcare a Human Right?

*The NHS holds a special place in the hearts of most Britons to the extent that it was featured in the opening ceremony of the London Olympics and according to Lord Ashcroft's poll published in the Guardian was cited as one of the main reasons for how they voted by 36 % of No voters and 54 % of Yes voters in the Scottish Referendum.*

With party conference season upon us we can again expect the future of the NHS to be constantly in the news often illustrated with stories of apparently unfair denial of a treatment to one patient freely granted another only a few miles away. How do we ensure the system is "fair" and indeed should we go further and enshrine the right to health as a human right?

Article 25 of the United Nations' Universal Declaration of Human Rights 1948 states that "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services." The European Convention on Human Rights however does not include health care perhaps because unlike the broad aspirations of the UN declaration the European Convention grants individuals enforceable legal rights. This is the rub then – most people are likely to support a general aspiration to broad access to healthcare and to support the idea that healthcare should be delivered in a non-discriminatory way but as science advances and financial resources are always limited some limitation on medical treatment is inevitable. How then can this be reconciled with the growing demands for healthcare to be treated as an enforceable human right? This was the topic at a recent

International Bar Association Conference in Edinburgh that brought together legal scholars and social scientists from around the world.

Probably the worst situation is that which has developed in Brazil where access to healthcare is guaranteed by the constitution. This has resulted in those denied treatment under general policies seeking redress in the courts. The courts of course have only to consider the situation of that individual before them and the strict wording of the law and not the overall consequences for health policy should the treatment they order provided to that individual be rolled out to everyone in a similar situation. Claudia Osorio, a Senior Researcher at the Sergio Arouca National School of Public Health in Brasil outlined a situation where litigation was growing exponentially and where around 95% of actions seeking redress were successful.

Another approach can be to have constitutional clauses that cannot be enforced in court such as in Nigeria where the constitution calls on government to develop policies to ensure the adequate provision of health facilities but does not give the citizen any right to seek redress in the court if the government fails in its eyes to take appropriate action. While this may avoid the Brazilian problem it does raise questions as to the point of the constitutional provision.

The South African constitution has probably the most detailed clauses on the right to healthcare which attempt to balance individual rights with broader national priorities and South Africa's obligations under international treaties. Citizens do have enforceable rights under the constitution but the courts have generally upheld government's rights to set national priorities even where that means denying particular treatment to certain individuals.

Again we have to consider whether trying to handle this sort of matter through a constitution guarantees any wider or fairer allocation of healthcare than the more administrative approach within healthcare providing organisations in say parts of Europe. The IBA conference failed to reach any conclusions as to whether legal redress offered a practical way forward and if so in what circumstances. Of course the best solution would be cheap effective treatments that allowed more people to be treated for less money and for social changes to lead to more disease being prevented but that is a much bigger topic

*By Patricia Barclay  
Bonaccord*



# Ebola

## the debate between clinical need and economic reality

The deadly outbreak of the ebola virus in West Africa in February 2014 initially went largely unnoticed by the global media even though it is one of the world's most frightening illnesses.

Cases were detected first in Guinea but quickly spread to neighbours Sierra Leone and Liberia and, having now claimed more than 1,000 lives and captured the attention of nations across the world, the main focus has tended to be on containment of the virus.

However, there are signs that research into the development of a drug to treat, or vaccinate against, ebola is making significant progress thanks to research being conducted by scientific teams around the world.

The World Health Organisation has reacted to the crisis by saying that largely untested drugs can be used on victims in West Africa given the severity of the situation and the need to bring it under control quickly.

Promising as some of the treatments may be, the outbreak has nevertheless brought into sharp focus the fact that drug research companies are first and foremost commercial entities that must ask themselves if tackling an illness prevalent in poor, under-developed countries with under-funded health services, makes commercial sense.





CONTINUED ON PAGE 42





## What is ebola?

At the heart of the debate is a virus which is terrifying because, up until now, there is no known cure and also because of the severity of its symptoms and the high rate of deaths in those infected - some estimates suggest that up to 90 per cent of those infected die. Others say it is at least 40 per cent.

The Ebola virus disease, which used to be called Ebola haemorrhagic fever due to the high level of bleeding, was named after the river in the Democratic Republic of the Congo where one of the first two villages to report cases in 1976 was located. The other was in Sudan.

Ebola is a viral illness that comes from direct contact with infected living or dead rainforest animals, including chimpanzees, gorillas, monkeys, fruit bats, forest antelope and porcupines, and can be passed from one human to another in blood and bodily fluids and secretions, but also beds, sheets, clothes or other surfaces that have come into contact with a sick person.

The early signs are sudden fever, intense weakness, muscle pain, headache and a sore throat. Vomiting and diarrhoea follow.

The kidney and liver are affected and there can be both internal and external bleeding, including from the eyes.

Patients are infectious once the symptoms show, which is two to 21 days after they have contracted the virus, but because of the lack of a cure or vaccine, containment has so far been seen as key to the strategy against ebola.

### Containing ebola

Those suffering from the illness need intensive care, with intravenous fluids or oral rehydration salts and must be kept in isolation and their nurses and visitors must wear full protective suits.

Care can include:

- Good nursing care
- Oxygen and devices that help with breathing
- Intravenous fluids to maintain fluids and electrolytes
- Medications to control fever, help the blood clot, and maintain blood pressure
- Antibiotics to prevent secondary infections.

For health professionals treating outbreaks, viewed as one of the highest at-risk categories of infection, it is also important to focus efforts on the community where the outbreak began. In the past, that has usually been villages in close proximity to rainforests.

The big concern for nations outside West Africa is the capacity of ebola to spread across the world, the risk of which rests with the time it takes between infection and noticeable symptoms, meaning that somebody with the virus could theoretically get on a plane and spark an outbreak – probably in a hospital – anywhere in the world.

Virologist Dr Ben Neuman, of the University of Reading in the UK, said: “The virus can spread person to person but requires direct contact with the body fluids of an infected individual or corpse. This virus is not transmitted by the respiratory route - you cannot catch ebola as you would the flu.

“While it is possible in theory to transmit ebola fever sexually, usually the virus is spread to family members and hospital staff who tend the sick. The other common route for infection is at public open casket funerals of ebola victims.”



Containment can be very effective, according to Dr Tim O'Dempsey, a senior Lecturer in Tropical Medicine at the Liverpool School of Tropical Medicine (LSTM) in the UK, who has been a key part of the WHO response and spent a month in Sierra Leone earlier this year.

LSTM clinical staff routinely manage critically ill patients at the Tropical and Infectious Disease Unit at the Royal Liverpool University Hospital and Dr O'Dempsey said: "The issue in West Africa is one of poorly resourced health systems.

"Our experience in Sierra Leone was that if health services were properly resourced, with correctly trained medical staff, between 40 and 60 per cent of people who present with the symptoms can survive.

"We were finding that adopting the right infection control systems was allowing us to make a difference.

"We know how to treat ebola. The key is using the right procedures and good communication but the outbreak in West Africa has revealed weak health systems and, if you become ill and know that your local health centre is under-

resourced, you are unlikely to go there.

"The truth is that this illness is treatable. The figures for 90 per cent death rates relate, I think, to earlier outbreaks and are frightening but our experience is that death rates can be lower than that."

During the latest outbreak, world governments have tried to help minimise that risk of the virus spreading outside West Africa.

The UK Department for International Development, for example, announced a £2m aid package to partners, including the International Federation of the Red Cross and Médecins Sans Frontières that are operating in Sierra Leone and Liberia. The European commission said it would allocate an additional £2m (£1.6m) to help contain the spread of the disease.

Dr Neuman believes that such an approach will help because of inherent weaknesses in the virus.

He said: "There is a possibility of ebola coming to the UK but it's very unlikely. The virus remains very weak, fragile, and transmits very inefficiently.

## Vaccine work is fast-tracked

Human trials of a candidate ebola vaccine, being co-developed by the US National Institutes of Health (NIH) and GlaxoSmithKline, are to be accelerated with funding from an international consortium in response to the epidemic in west Africa.

A £2.8 million grant from the Wellcome Trust, the Medical Research Council and the UK Department for International Development (DFID) allowed a team led by Professor Adrian Hill, of the Jenner Institute at the University of Oxford, to start safety tests of the vaccine alongside similar trials in the USA run by the National Institute of Allergy and Infectious Diseases.

The consortium's funding will also enable GSK to begin manufacturing up to around 10,000 additional doses of the vaccine at the same time as the initial clinical trials.

The candidate vaccine is against the Zaire species of Ebola, which is the one circulating in west Africa, and uses a single ebola virus protein to generate an immune response.

Pre-clinical research by the NIH and Okairos, a biotechnology company acquired last year by GSK, has indicated that it provides promising protection in non-human primates exposed to ebola without significant adverse effects.

Professor Adrian Hill, Director of the Jenner Institute at the University of Oxford, said: "The tragic events unfolding in Africa demand an urgent response. In recent years, similar investigational vaccines have safely immunised infants and adults against a range of diseases including malaria, HIV and Hepatitis C. We, and all our partners on this project, are optimistic that this candidate vaccine may prove useful against ebola."

Dr Jeremy Farrar, Director of the Wellcome Trust, said: "This epidemic has shown how difficult it can be to control ebola. How useful drugs and vaccines might be in complementing existing public health interventions can only be assessed in epidemics."

Professor Myron Levine, Director of the University of Maryland School of Medicine Center for Vaccine Development, said: "This is an extraordinary effort of multiple groups working together to bring a promising early stage candidate Ebola vaccine to field tests in west Africa in record time. On short notice, the project partners have contributed enormous energy, time and resources to respond to the Ebola disease calamity."

“

*There is a possibility of ebola coming to the UK but it's very unlikely. The virus remains very weak, fragile, and transmits very inefficiently.*

**Dr Ben Neuman**

Virologist, University of Reading

”







"Ebola is spreading in West Africa among a mostly rural population due to a lack of trust and education about medical intervention - that does not exist in the UK."

"We also have a massive infrastructure in place to prevent diseases like ebola from coming to Britain - highly trained people, equipment and technology that will be mobilised if a case arrives. One reason that we haven't heard more about similar diseases in the past is because our public health workers are good at their jobs. There is virtually no risk to the general population."

"The World Health Organisation declaring a public health emergency of international concern is a big forward step in the fight against this dangerous disease. It is a rare event, something only done in the past for H1N1 'swine' flu in 2008 and the ongoing polio outbreak."

"This will make the vast resources of the United Nations such as funds, experts and

equipment, available to help stop ebola. This should bring the outbreak under control although it's likely it won't be stopped completely until after Christmas."

"The WHO also recommended commonsense procedures to stop the spread of infection, such as taking temperatures of incoming passengers from airports in the affected region."

"Educating and gaining the trust of the people likely to be infected are key to preventing future outbreaks."

### *Can a drug treatment be found?*

Running alongside containment has been work on a drug-based treatment. For example, Canadian company Tekmira Pharmaceuticals Corporation recently announced that the US Food & Drug Administration (FDA) has allowed the potential use of its drug TKM-Ebola in individuals infected with ebola.

TKM-Ebola, an anti-Ebola virus RNAi therapeutic, is being developed under a \$140 million contract with the US Department of Defense's Medical Countermeasure Systems BioDefense Therapeutics Joint Product Management Office.

Earlier preclinical studies demonstrated that when the drug was used to treat previously infected non-human primates, the result was 100 per cent protection from an otherwise lethal dose of Zaire ebola virus.

Dr Mark Murray, CEO and President, Tekmira Pharmaceuticals, said: "We have been closely watching the ebola virus outbreak and its consequences and we are willing to assist with any responsible use of TKM-Ebola."

"This current outbreak underscores the critical need for effective therapeutic agents

to treat the ebola virus. We recognise the heightened urgency of this situation and are carefully evaluating options for use of our investigational drug within accepted clinical and regulatory protocols."

For Dr Neuman, at the University of Reading, economics remain a stumbling block. He said: "Pharmaceutical companies are businesses - they last only as long as they continue to make money."

"While a new wonder-drug may be hugely profitable in the short-term, the financial health of a company depends on its drug development pipeline, the ability to bring a steady flow of new drugs to the market in the long term. A company is only as strong as its pipeline."

"The potential ebola medications that are being considered all work well at stopping the virus in the lab and in infected animals. A person with ebola might have to be treated for a month or more and the side effects of large amounts of treatment over a long time are tough to predict."

"There are reasonably strong humanitarian and ethical grounds to allow experimental ebola therapies for infected people."

Dr O'Dempsey, at Liverpool, said: "There are several considerations with the drugs being developed, both the treatments being developed, and the vaccine being developed in Canada."

"There are ethical issues with using drugs that are not fully tested. Who do you give them to, will they work, will they do harm?"

"There is also a dilemma for companies developing drugs for a range of tropical diseases. Usually they will be used to benefit poor people and there is little commercial gain to be achieved in developing them for such markets."





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# Life or Death

## The importance of Cold Chain Supply

*All over the world, drug companies are producing medicines and treatments that are saving lives but when the pharmaceuticals leave the manufacturing plant that is only half the story.*

Crucial to the success of the drugs is their safe delivery to hospitals, clinics and pharmacies and many of the consignments have to be kept at strictly-observed temperatures as they embark on their long journeys.

To ease the worry, many businesses outsource the delivery of their products to specialists in what is known as Cold Chain Logistics.

The success of drug treatments is often down to the skills and specialist equipment used by these logistics firms in meeting what is acknowledged as one of the biggest challenge that pharmaceutical industries face. Getting their products delivered safely.

The result is that cold chain logistics companies are transporting, and storing, vast amounts of pharmaceutical products around the planet, ranging from blood plasma and tissues to drugs and chemicals, clinical trial materials to gel packs.

It has become a huge industry; it is estimated that in the UK, for example, the temperature-controlled logistics market is worth an estimated 24% of the country's total £96bn road transport market

The potential is there for further growth across the globe. According to the World Health Organisation, the global pharmaceutical market is valued at USD 300 billion and is expected to grow by USD 400 billion within three years.

India alone, a leading player in global healthcare industry, earns 60% of its pharmaceutical revenues through exports, a figure which grew by 19% between 2008 and 2012.

And it all needs distributing. Cold chain companies, which are common in the food and pharmaceutical industries as well as in some chemical shipments, have the task of maintaining specific temperatures which can be different for different products.

Keeping the temperatures constant is vital in the case of drugs to ensure that they retain their efficacy. Take vaccines as an example; they are very often bound for clinics in hot climates which are served by poorly developed transport networks.

The potential for delays at the ports and on the road in such countries is huge and it is vital that the temperature of the products are maintained however long the vehicles are held up.

That is why specialised logistics companies invest heavily in their vehicles and the on-board equipment required to keep the drugs at the right temperature.

They are also increasingly making use of specialised warehousing fitted with the latest in temperature and humidity controls so that the products can be stored safely either before starting their journey or en route.

That includes securing compounds and vehicles against criminals, which is a huge global business. In 2013, FreightWatch International, a global logistics security services company that aims to mitigate risks associated with cargo theft, revealed in its Global Cargo Theft Assessment that cargo theft rates in Europe increased 24% on average from 2011, and were on the rise in Asia as well.

Cargo theft rates in North, Central and South Americas remained consistent with prior years with the greatest risk of cargo theft existing in Brazil, Mexico and South Africa.

Over the previous decade, more than 10,000 cargo theft incidents were reported in Brazil. In 2012, nearly 6,800 incidents were reported





in São Paulo alone. In Mexico, more than 6,000 cargo theft incidents were reported in 2012, the majority of them involving truck hijackings. In South Africa, more than 800 truck hijackings were reported.

Although these figures cover everything from food and drink products to high-value consumables, such as electronics, pharmaceutical drugs are a big market and logistics companies take the threat of theft seriously.

Packaging is also an essential element in the successful delivery of temperature controlled products. Selecting the correct packaging system requires an understanding of logistics, primarily the environment to which the shipment will be exposed during transit.

There is so much that can go wrong if the packaging is inadequate, including ; temperatures dropping too low and humidity having an adverse affect on the product.

All of these considerations make the cold chain business an expensive one, with all sorts of costs, obvious and hidden but the investment is necessary.

Failure to get distribution and storage right may have disastrous effects; a drug which is proved to work may actually fail if its transportation conditions were poor meaning that lives may be placed at risk. In the case of vaccines, there is the danger of an outbreak of a disease which would otherwise remain under control.

The need to safely and correctly transport such shipments is why the industry has so many regulations and why the cold chain distribution process is seen as an extension of the good manufacturing practices to which drug and biological product companies are required to adhere.

The regulations are enforced by the various health regulatory bodies around the world and, to ensure that they comply with the regulations, cold chains have sophisticated quality management systems, which are constantly analysed, measured, controlled, documented and validated to ensure that there is no negative impact to the quality of the drugs being transported.

A central part of the process is the logistics companies' understanding of the different

rules and regulations that exist in different countries, each one of which needs specialised navigation. The rules in Africa, for example, may be different than those in India.

Because freight is not an exact science, and because so many things can come into play once a load is on its way, a good logistics company will make sure that they not only understand the local differences but also keep the client informed of each load's progress.

To that end, a good logistics company will make use of the best in new technology, including online tracking systems which allow them to know exactly where a shipment is at any given time.

It's a lot of effort but worth it - the temperate-controlled logistics industry is, quite literally, a life-saver.

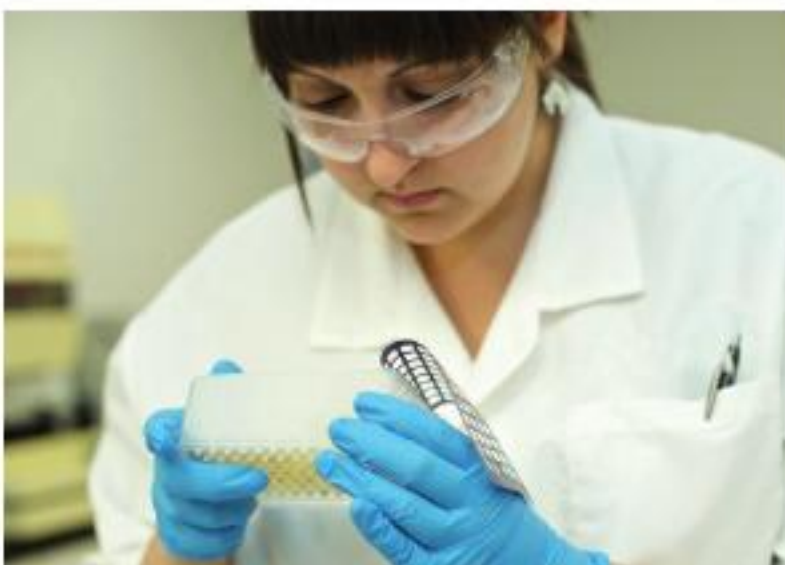




# Regulatory compliance is the top supply chain concern for healthcare companies globally

Complying with ever-changing regulations continues to be the top concern for healthcare executives, according to the 2014 UPS Pain in the (Supply) Chain survey. Six out of ten executives mentioned regulatory compliance as their top supply chain issue. Further, 79% of respondents plan to invest in regulatory expertise and increased staffing levels as a strategy to address this challenge.

The key driver for concern is the changing regulatory landscape, including the revision of the EU Good Distribution Practice (GDP)



guidelines and changing customs procedures. Companies are struggling to interpret and stay up to date with the changes. Almost half (49%) of executives interviewed said that individual country regulations are the top barrier for export and expansion.

Product protection is another primary concern, cited by 46% of respondents. The increasing sophistication of counterfeits (48%), poor supply chain visibility and too many hand offs (40%), and inadequate law enforcement (35%) were confirmed as the biggest challenges. Regarding product security, executives are also concerned with product damage or spoilage, which was stated by 40% of respondents.

To overcome risks related to the evolving regulatory environment and supply chain security, companies are focusing on two key areas: collaboration and partnership and technology investments. One in five healthcare companies is already outsourcing three quarters or more of its supply chain budget. To stay abreast of changing regulatory requirements, more than half (57%) of surveyed executives are planning to hire

outside consultants, while up to 54% plan to partner with experienced distribution firms. Distribution partners can help manufacturers navigate and comply with regulations, as these firms have the expertise to handle



special service requirements for temperature-sensitive storage and distribution. UPS, for example, maintains a formalized quality management system and independent quality assurance group to monitor new and proposed regulations to maintain the necessary

Survey participants cited the following supply chain issues as concerns

● North America ● Global







processes and document control. This allows healthcare manufacturers to focus on their core business – developing products that positively impact patient care.

When it comes to technology, the main focus of executives is on investments that enable product visibility. According to the survey, almost seven out of ten executives (66%) are looking to invest in serialization and product verification technology, while 53% are considering to invest in temperature control and monitoring technologies. Building effective visibility systems, however, is expensive and complex. Competent logistics providers can integrate their own networks with those of their customers and eliminate the need for extra investment while maintaining visibility across the entire supply chain.

Opportunity combined with frustration perhaps best describes the current status of the global healthcare industry. As the global healthcare market evolves, opportunities are developing in the form of new markets and products. However, frustrations have developed as a result of increasing and ever-changing government regulations. To maintain a global standard of compliance demands adept logistics planning and continuous stakeholder engagement. Every logistics solution must include contingency plans, along with a trained and specialized team to implement these plans. It's important to collaborate closely with customers and build a robust plan for keeping products on course at every stage of their journey. Healthcare manufacturers should choose their distribution partners based on their expertise and network, their proven ability to execute, and their willingness to stand behind their service with actionable quality programs.

For more information on the UPS Pain in the (Supply) Chain survey and to download an executive summary, visit [www.pressroom.ups.com/healthcare](http://www.pressroom.ups.com/healthcare).

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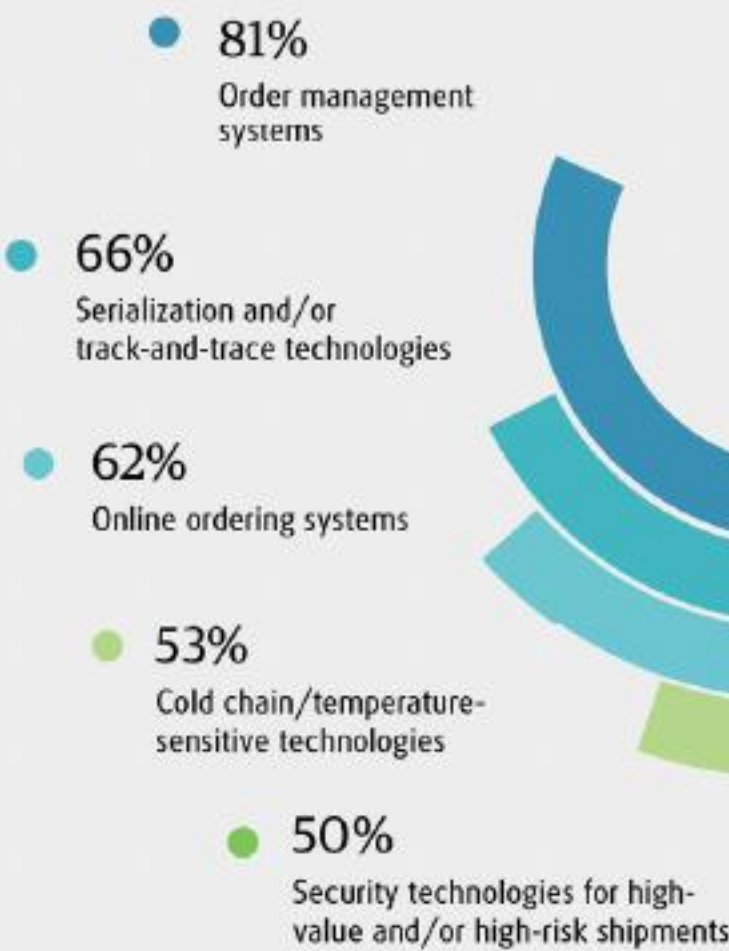


Globally, product protection remains a top supply chain concern for healthcare executives



Please rate the following supply chain issues which may or may not impact your business in the future. (Not all answer options are shown.)

Percentage of respondents globally citing planned technology investments by type in the next three to five years



Which specific technologies would you invest in to increase efficiencies and/or improve your competitiveness over the next three to five years?

Regulatory compliance



What are some of the strategies your company has utilized to successfully address regulatory compliance?



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# A simple idea that could change medical research

It is often said that the best inventions are the simplest. That is certainly the case with CryoXtract Instruments, whose CXT350 and CXT750 frozen aliquotting systems have the potential to revolutionise the world of frozen biospecimen storage in medical research.

CryoXtract's technology solves a longstanding problem for medical researchers: It allows them to access and core pieces of frozen biosamples, which run the risk of degradation once thawed.

Previously, researchers wishing to use part of a frozen sample had to completely thaw it, even if they only needed a small fragment. That meant the remaining sample either needed to be re-frozen, running the risk that it would be compromised when re-used, or discarded. CryoXtract's devices remove these problems because they extract only what is required without the need to thaw the remainder, rather in the way that researchers use ice-cores taken from the world's frozen wastes when researching climate change, but on an altogether much smaller scale.

Having the ability to use a single frozen sample multiple times will help bolster efforts to collect samples of blood, serum, plasma, tissue and others. Already, demand for biobanks, the centres around the world that store these samples, is accelerating amidst increasing recognition that the analysis of biospecimens could yield enormously beneficial insights into the evolution, causes and treatment of diseases such as cancer and cardiovascular disease, as well as neurodegenerative diseases such as Alzheimer's and Parkinson's. CryoXtract's simple and effective solution offers managers of biobanks and similar establishments a new way to safeguard the integrity of their rapidly growing number of samples.

It will also help to support the fast growth of another area of intense interest: Microbiome/ Microbiota research. This field of research endeavours to understand the relationship of our multitudinous microbial inhabitants of our intestines with the development of various diseases ranging from obesity and Type 2 diabetes to inflammatory bowel disease and ulcerative colitis.

The technology concept behind the CXT350 and CXT750 was invented by engineers and physicians at Harvard Medical School and Northeastern University in Boston, and is now distributed in the UK by Cambridge Bioscience.

CryoXtract offers two configurations of its automated systems, allowing them to be used in large or small facilities, from a freezer in a hospital research laboratory to a large automated biobank containing tens of thousands, if not millions, of samples.



The CXT750 is a fully automated, programmable robotic system that can process hundreds or thousands of samples at a time. It can reformat them into microtubes or microplates for immediate analysis, or into cryotubes for distribution to researchers in other laboratories or for longer-term frozen storage.

Its smaller cousin, the CXT350, is a slightly more hands-on but versatile instrument, which can be readily deployed to any laboratory around the world.

The systems reduce human error in sample processing, keep samples in a safe and ultra-cold state throughout, and ultimately improve the outcomes of analysis and the quality of the research on these samples.

Since the systems were launched within the last two years, the reliability they offer has been proving invaluable to scientists involved in everything from advanced molecular medicine to biomarker discovery, cancer research to neurodegenerative medicine, and to the study of probiotics and diagnostics in the field of human gut Microbiome research.

CryoXtract's proprietary technology removes multiple frozen aliquots from a single sample without exposing the parent repeatedly to the freeze/thaw cycles that can degrade critical molecules.

After the frozen cores have been obtained, the parent sample may be returned to storage still frozen for future processing, with researchers

secure in the knowledge that its integrity has been protected.

By eliminating the unnecessary exposure of samples to freeze/thaw cycles, CryoXtract's technology is also able to support critical R&D activities by prolonging the samples' useful life.

This helps to reduce the need to collect new samples, allowing researchers to streamline their sample aliquotting process and improve lab efficiencies. In particular, fewer freezers and liquid nitrogen storage tanks are needed, minimising the costs.

CryoXtract's technology is being used in core facilities, sample management facilities, clinical and research laboratories, forensics laboratories and drug discovery and development laboratories around the world. It's proving particularly useful to operators of biobanks and biorepositories.

With more countries and major companies establishing biobanks, and as the need to effectively manage their huge stocks without compromising samples becomes ever more urgent, the role of CryoXtract in offering an easy-to-use solution is becoming ever more attractive.

For a simple idea, the CryoXtract systems offer an opportunity to have a major impact in the world of frozen biomedical specimen storage.



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# Testo Saveris 2: Temperature and humidity monitoring re-invented.

*Thanks to Testo, temperature and humidity monitoring has been simplified.*

Monitoring temperature and humidity is important where incorrect climatic conditions can have drastic consequences; too low a temperature in pharmacy refrigerators can negatively influence the effectiveness of vaccines, or excessive air humidity in museums can damage the surfaces of valuable exhibits, and in food production too high a temperature can accelerate the spoiling of sensitive products.

The cost too many businesses that rely on stable temperature management can be excessive should a cooling or heating system malfunction leading to wasted stock, or worse.

Traditionally there have been two methods available for monitoring irregular fluctuations in temperature and humidity; data loggers and data monitoring systems. Data loggers are a very simple solution but a common issue is that information needs to be manually acquired and the logger does not always automatically in form users of excessive temperature fluctuations. The main disadvantage of data monitoring systems is their complexity, i.e. they require time consuming installation and maintenance, and are more often than not complex and expensive.

## Cloud based temperature and humidity monitoring.

The Saveris 2 system was developed by Testo's measurement technology specialists in Germany's Black Forest. They were set one simple task; design a solution so customers can monitor their temperature and humidity levels easily, anytime and anywhere, without



needing to compromise security or bother with time consuming software. In the current age this presented a number of challenges but they embraced the situation and have designed a remarkably simple and elegant solution.

Testo's developers decided to use cloud technology because it allows information to be stored remotely with access to the data as and when needed whilst providing the ability to be on the other side of the world and still be able to monitor and react to issues. This reduces the pressure on an individual, or team, to be constantly on site to keep measurement values under control. If temperature or humidity levels fluctuate beyond acceptable levels an alert is sent by SMS and e-mail to the parties' responsible, allowing action to be taken to prevent any loss of product.

Data is extracted and stored wirelessly and can be accessed by simply logging on to the secure cloud location allowing easy viewing of the information. This process simply relies on a standard internet browser, so no special software or configuration is needed and it can be accessed via a computer, tablet or smart phone. Equally, when on site with Saveris 2 you can scan each Saveris logger's built in QR code (see image), which will take you to the secure cloud page devoted to the data extracted from the logger in question, allowing speedy assessment of individual loggers.

Using their vast experience with temperature logging, Testo was aware many of their customers' businesses expand and change over the life of a product. So the Saveris 2 system has been designed with flexible expansion

capabilities with customers able to start with a simple setup which can be added to over time and making it easy for the system to grow as their business develops.

## Flexibility with security.

As of autumn 2014, the Testo Saveris 2 will be available in various different versions via [www.testolimited.com](http://www.testolimited.com) and from selected specialist dealers. There are five different temperature and humidity probes available, as well as three licensing models for the use of the Cloud.





# Smarter Insulated Packaging

*From chilled food products to temperature sensitive pharmaceuticals, wool is at the heart of a revolution in the insulated packaging being used for temperature controlled logistics. Significantly, it's not just the pressures to find more sustainable packaging systems that's driving the change but which packaging offers the best performance.*

Hygroscopic properties of wool make it nature's 'smart fibre' for insulation purposes and multi award-winning packaging designer, Angela Morris, has harnessed this in developing the simply ingenious Woolcool insulated packaging.

Angela Morris initially developed Woolcool as a sustainable alternative to polystyrene insulated packaging for National Trust farmers to dispatch meat boxes to customers. Woolcool is made using natural fleece which is washed and scoured without using harmful chemicals and sealed within recyclable, food grade film to make insulation liners for a range of rigid, cardboard delivery boxes and pouches.

Rigorous testing has proved that Woolcool packaging maintains contents below the legal requirement for food of 5°C for at least 24 hours and even well over 48 hours. Woolcool has also been proven to keep contents consistently cooler for longer than the most widely used polystyrene boxes.

With such impressive performance results, along with the unrivalled 'green' credentials

of wool over polystyrene, Woolcool has increasingly been adopted by a host of direct delivery food suppliers, ranging from Abel & Cole to Fortnum & Mason.

Angela Morris: "The performance and versatility of Woolcool means our packaging isn't simply a niche product for eco-friendly, ethical food retailers but also every business trying to tap into the booming direct delivery food market. Our proven results mean food retailers can ship orders with confidence, by post or courier, the length and breadth of the UK and beyond. Woolcool is at the cutting edge of food sector developments, whether we're supplying major players in the mail order recipe kit sector, such as Hello Fresh and Gousto, or the growing numbers of online diet and health food businesses".

Building on this success for chilled food logistics, Woolcool is now expanding into the delivery of highly temperature sensitive pharmaceuticals. Morris explains: "It is absolutely critical that many medicines and vaccines are maintained within tight temperature ranges of 2°C to 8°C and 15°C to 20°C, during complex supply chains and significant variations of ambient temperatures. The UK government backed Technology Strategy Board recognized the potential of Woolcool and we have been awarded funding to specifically develop our insulated packaging for the pharmaceuticals sector".

The TSB investment in Woolcool reflects growing concerns over failings in the existing

cold chain logistics of temperature sensitive pharmaceuticals, which culminated in the 2013 publication by the European Commission of 'Guidelines on Good Distribution Practice of Medicinal Products for Human Use'. The guidelines are intended to ensure the strictest procedures at every stage of the supply chain and greater accountability from wholesalers to distributors, recognising that 'Today's distribution network for medicinal products is increasingly complex and involves many players'. When auditing and analysis of existing packaging reveal failings in complex supply chains, specially designed Woolcool packaging could hold the answer, having already been validated by key customers to the Medicines and Healthcare Products Regulatory Agency (MHRA) standards of maintaining internal temperatures between 2°C and 8°C for more than 72 hours.

In the pharmaceuticals sector, one of the world's leading wholesalers of veterinary medical supplies, Henry Schein Animal Health, has already switched to bespoke Woolcool insulated packaging, as well as Dental Directory, the UK's largest, British owned, full service dental dealer. Angela Morris: "We're incredibly excited about the results Woolcool is achieving and we are now setting unrivalled standards for pharmaceuticals logistics that will be vital for compliance with the EU GDP Guidelines".

More information at [www.woolcool.com](http://www.woolcool.com)




“

*There is a growing realisation that current oil-based insulated packaging materials such as Expanded Polystyrene (EPS) or Polyethylene are not only unsustainable but also failing to provide consistent insulation performance for temperature controlled logistics*

”

Angela Morris  
CEO of Woolcool






# WOOLCOOL

## It's fresher with Woolcool

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# Crime Scene

## International efforts target improvements in food safety

*Food safety has never been higher on the international agenda as understanding the impact of what we eat on our health becomes ever more important.*

As debates rage about the potential damage caused by the likes of salt and sugar, scientists are also concerned by everything from the capacity for contaminants to get into food to the dangers of criminal fraud and the link between food and germs.

Worldwide, the food industry is increasingly effective at guaranteeing the safety of what we eat but there are always risks. Scientists are playing their part in work to reduce those risks.

One of the major areas for research is the threat posed from food to young people and the United Nations body responsible for setting food safety standards recently adopted guidelines which set out maximum levels of lead in infant formula and arsenic in rice.

The UN Food and Agriculture Organization and the World Health Organization said that no more than 0.01 mg per kg of lead should be permitted in infant formula and no more than 0.2 mg per kg of arsenic permitted in rice.

They say that infants and young children are particularly vulnerable to the toxic effects of lead, suffering adverse health effects to the brain and nervous system.

Often found in the environment, lead can end up in ingredients used in the production of infant formula. Levels can be controlled and monitored by sourcing raw materials from areas where lead is less present.

Long-term exposure to arsenic can cause cancer and skin lesions and has been associated with heart disease and diabetes. Ingested arsenic can also severely damage the nervous system and brain.

Like lead, arsenic is found in the environment and is present at high levels in the groundwater and soil in parts of the world. The danger is that it can enter the food chain by being absorbed into crops.

Rice, a major staple food for millions of people, absorbs arsenic more than other crops but, according to the UN Food and Agriculture

Organization and the World Health Organization, the problem can be reduced by improved irrigation and agricultural practices including growing crops in raised beds instead of flooded fields.

### **No country immune from problems**

It's not just the developing world that causes concerns. According to global food source monitoring company Food Sentry, the US was one of the top ten countries with the most food safety violations in 2013.

Food Sentry recorded more than 3,400 verified violations associated with products exported from 117 countries. At the top of the list was India, with 380 of the incidents identified worldwide. China followed with 340, Mexico with 260, France with 190 and the US with 180. Vietnam, Brazil, the Dominican Republic, Turkey and Spain completed the top ten.

The incidents concerned mainly raw or minimally processed foods, including seafood, vegetables, fruits, spices, dairy, meats, grains, and nuts and seeds.

Food Sentry says that more than a third of the problems were caused to 'excessive or illegal pesticide contamination.' The next main causes were pathogen contamination and insanitary conditions.

Food Sentry was created by a team of food analysts to protect US consumers and Senior Intelligence Analyst Zak Solomon said: "Food safety violations are nothing new. They've just been receiving a lot of attention lately and rightly so. We import from every single one of the countries in the top ten."







CONTINUED ON PAGE 60





Indeed, the US Food and Drug Administration and the government of Mexico's National Service for Agro-Alimentary Public Health, Safety and Quality and Federal Commission for the Protection from Sanitary Risks recently agreed a partnership to promote the safety of fresh and minimally-processed agricultural products coming out of Mexico.

FDA Commissioner Margaret A. Hamburg, M.D. said: "To be successful as regulators, the FDA must continue developing new strategies and partnerships that allow us to more comprehensively and collectively respond to the challenges that come with globalisation. The FDA is working with our Mexican government counterparts as well as stakeholders from industry, commerce, agriculture, and academia to ensure the safety of products for American and Mexican consumers."

Mexico is the leading exporter of FDA-regulated foods into the United States; leading categories include fresh vegetables (\$4.6 billion), fresh fruit excluding bananas (\$3.1 billion), wine and beer (\$1.9 billion) and snack foods, including chocolate (\$1.5 billion).

Michael R. Taylor, the FDA's Deputy Commissioner for Foods and Veterinary Medicine, said: "Food safety partnerships must extend well beyond government so we are engaging the private sector as well because their food safety practices, coupled with government standards, are what make food safe."

### *Food fraud a concern*

A growing worry for food scientists is fraud which could compromise food chains, and scientists at Queen's University in Belfast, Northern Ireland, recently received £500,000 to investigate the global problem.

The two-year project will investigate vulnerabilities in food supply chains and look at ways to improve consumer trust in food and producers.

Queen's was awarded one of five grants from the 'Understanding the Challenges of the Food System' programme run by the Economic and Social Research Council and the Food Standards Agency, under the Global Food Security initiative.

Professor Chris Elliott and Dr Moira Dean from the Queen's Institute for Global Food Security and their colleagues from the School of Law & Institute for Study of Conflict Transformation, in collaboration with Dr John Spink from Michigan State University, will undertake the analysis.

Professor Elliott said: "There are a growing number of reports of fraud and criminal activity in global food supply systems. These are causing huge concerns to governmental agencies and to the food industry. Consumers are losing trust in the safety and quality of what they purchase.

"This Queen's University led study will play a very important role in ascertaining where the major vulnerabilities are and how best to deal with them. Helping to restore consumer trust is a key objective of our work.

"The current food protection systems are not designed to look for the never-ending number of potential adulterants that may show up in the food supply. As criminal activity by design is intended to elude detection, new tools and approaches to the supply chain management are called for.

"This project will explore how other countries deal with issues of food safety and analyse legal law cases which relate to fraud. Based on an assumption that fraudsters will exploit any intelligence gathering system it will also examine current and potential models of data collection and intelligence sharing and test their vulnerabilities to future fraudulent attacks. This will help to develop a novel data collection sharing system that is more robust and secure."

Professor Paul Boyle, Chief Executive of the Economic and Social Research Council, said:

"We're delighted to come together with the Food Standards Agency to fund innovative research into important areas which underpin UK food security. The projects that are being funded will deal with priorities such as resilience, safety and security, food price volatility and supply chain management - all of which are recognised as yielding important social science research challenges to be addressed for the mutual benefit of the food industry and consumers alike."

### *The dangers posed by food-borne germs*

Another big concern relates to the capacity of meat to harbour germs such as salmonella and the ability of drug treatments to be effective.

That concern was highlighted by a new report published in America that shows that antibiotic resistance in food-borne germs remains a public health threat.

According to the Centers for Disease Control and Prevention (CDC), each year antibiotic-resistant infections from food-borne germs cause 430,000 illnesses in the United States alone. Salmonella, which comes from food and other sources, causes 100,000 illnesses in the United States each year.

The most recent data, for 2012, showed that, although drug resistant salmonella has decreased during the past ten years and resistance to two important groups of drugs – cephalosporins and fluoroquinolones – remained low, there is still a concern about Salmonella typhi.

The germ causes typhoid fever and the data suggests that resistance to quinolone drugs increased to 68 per cent, causing concerns that one of the common treatments for typhoid fever may not work in many cases.

Also, one in five Salmonella Heidelberg infections was resistant to ceftriaxone, a cephalosporin drug. This is the same Salmonella serotype that has been linked to recent outbreaks associated with poultry.

Resistance to Ceftriaxone is a problem because it makes severe Salmonella infections harder to treat, especially in children.

Robert Tauxe, M.D., M.P.H., deputy director of CDC's Division of Foodborne, Waterborne, and Environmental Diseases, said: "Our latest data show some progress in reducing resistance among some germs that make people sick but, unfortunately, we're also seeing greater resistance in some pathogens, like certain types of salmonella.

"Infections with antibiotic-resistant germs are often more severe. These data will help doctors prescribe treatments that work and to help CDC and our public health partners identify and stop outbreaks caused by resistant germs faster and protect people's health."



# Why choose the National Agri-Food Innovation Campus as the home for your business?

The campus offers a rare opportunity for organisations to grow within a unique scientific environment. Those based on-campus benefit from state-of-the-art equipment, a top range of support services, an enviable location and unique opportunities to interact with world-class scientists and businesses all working at the interface of government, academia and industry.

The campus hosts the headquarters and main laboratories of The Food and Environment Research Agency (Fera) - the Government's principal applied research organisation in the area of food and environmental safety, security and integrity. A key part of the UK's innovation ecosystem, Fera acts as a catalyst for the creation of high value, knowledge rich employment opportunities.

The campus is home to a lively mix of public and private sector organisations and welcomes business from a wide range of sectors whilst focussing on providing a home for agri-food focussed organisations and those in life sciences covering plant, animal and human health.

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# When the worlds of sport and medicine collaborate

*There was a time when sports science was viewed by many as a track-suited football trainer running onto the pitch clutching a magic sponge. It was all rather rudimentary, all groin strains and hamstrings.*

However, recent decades have seen dramatic changes in the approach taken to performance by those involved in many sports.

Every major sports team has a team of health professionals specialising in everything from medicine to psychology and there are clear overlaps between their work and advances being made in the general medical field.

Football is one of the sports leading the way. Carl Wells PhD, BSc (hons), an accredited sport scientist and Sport Science Lead, Perform at St. George's Park, the FA's football centre in the UK Midlands, said that the game has had to turn to science given the way the sport has changed.

He said: "Sports science in the game has really emerged in the past ten to twelve years.

"Previously, you would hear of players doing a lot of running, going for long plods, which may have had a good psychological effect but did not help with the specific demands of the sport.

"It did not take account of the

parameters under which the body operates in football, the loads placed on the body when accelerating and decelerating, the multi-directional nature of the game.

"However, as the game has become faster, players have evolved to become quicker, fitter and more powerful, and sports science is increasingly used to measure the effect that has on their bodies.

"Today, sports science underpins everything they do and the players are tested to measure the effect that playing is having using the latest scientific knowledge. It's about the use of evidence-based practice to ensure optimum performance gains.

"Clubs at all levels of the game are making use of the latest scientific knowledge and that is having a knock-on effect as we better understand the demands that intense intermittent physical exercise has on the human body."







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## VITAMIN D RESEARCH CASTS LIGHT ON SPORTING PERFORMANCE

Another example of sport and science overlapping is work being done in America on the impact of Vitamin D on athletic performance.

According to analysis published in the American College of Sports Medicine's Health & Fitness Journal, a lack of what is often known as the 'sunshine vitamin' may affect muscle function and fitness levels, reducing sporting prowess and having wider health ramifications.

Identifying the problem is important not just for sports men and women but also for the wider population and study author Stella Lucia Volpe, R.D., a professor of nutrition science at Drexel University, has welcomed the fact that blood tests for vitamin D levels are becoming more common as part of routine visits to the doctor.

The research outlines the dramatic effect of Vitamin D deficiencies on athletic performance. In one research programme, professional athletes recorded improved sprint times and better vertical jumps when they took supplements for eight weeks. Ballet dancers reported greater strength and vertical jump height as well as fewer injuries when they took a daily supplement for four months.

According to the study, sufficient vitamin D levels leads to reduced levels of inflammation, pain, and weakness, improved exercise capacity and better protein synthesis within the muscles, all crucial to anyone doing sport.

The challenge is that the body can not make vitamin D on its own rather obtaining it from the sun (a few minutes of exposure a day is all you need) or from foods, like fatty fish or fortified milk and orange juice.

Stella Vope says that deficiencies are common, especially during winter months and in people who live farther from the equator.

Stella said: "The reason for this increased prevalence of vitamin D deficiency is not yet known. It is perhaps due to increased use of sunscreen, people going in the sun less, people covering themselves more. However, it may also be a result of more people being analysed for vitamin D.

"Vitamin D blood analysis is not routinely done but has been requested much more often by physicians over the past five years or so.

"If it were up to me, I think we all should be analysed once a year or at least once every other year."

Vitamin D deficiency is also associated with a substantially increased risk of dementia and Alzheimer's disease in older people, according to an international team led by Dr David Llewellyn at the University of Exeter Medical School in the UK.

The team discovered that elderly Americans who took part in the Cardiovascular Health Study and were moderately deficient in vitamin D had a 53 per cent increased risk of

developing dementia of any kind, and the risk increased to 125 per cent in those who were severely deficient.

Similar results were recorded for Alzheimer's disease, with the moderately deficient group 69 per cent more likely to develop this type of dementia, rising to a 122 per cent increased risk for those severely deficient.

Dr Llewellyn said: "We expected to find an association between low Vitamin D levels and the risk of dementia and Alzheimer's disease, but the results were surprising – we actually found that the association was twice as strong as we anticipated.

"Clinical trials are now needed to establish whether eating foods such as oily fish or taking vitamin D supplements can delay or even prevent the onset of Alzheimer's disease and dementia. We need to be cautious at this early stage and our latest results do not demonstrate that low vitamin D levels cause dementia. That said, our findings are very encouraging, and even if a small number of people could benefit, this would have enormous public health implications given the devastating and costly nature of dementia."

Research collaborators included experts from Angers University Hospital, Florida International University, Columbia University, the University of Washington, the University of Pittsburgh and the University of Michigan. The study was supported by the Alzheimer's Association, the Mary Kinross Charitable Trust, the James Tudor Foundation, the Halpin Trust, the Age Related Diseases and Health Trust, the Norman Family Charitable Trust, and the National Institute for Health Research Collaboration for Leadership in Applied Research and Care South West Peninsula.



## EXERCISE CRUCIAL IN TACKLING OBESITY

Another team of US-based scientists have drawn on elements of sports science in the battle against obesity.

A majority of Americans are overweight or obese, which is a key reason for the rapid rise in common diseases like diabetes, heart disease, cancer, high blood pressure and more.

According to a paper published in the official journal of the American College of Sports Medicine, the benefits of exercise are crucial.

Study co-author and ACSM member Melinda Manore of Oregon State University, said: "It is time we collectively move beyond debating nutrition or exercise and focus on nutrition and exercise.

"Nutrition and exercise professionals working collaboratively, combined with effective public health messaging about the importance of energy balance can help America shape up and become healthier.

"Our health professionals are currently working in silos and must work together to educate and promote energy balance as the key to better health.

"The obesity crisis is one of the greatest public health challenges of our generation. Energy balance can help us work toward a solution so our children aren't saddled with the same health challenges we currently face."





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## Will Man ever run the 100m in less than nine seconds? \*

By Polly McGuigan

Lecturer in Biomechanics, and Aki Salo, Senior Lecturer in Sport Biomechanics, both from the University of Bath in the UK.

*It is never easy to run 100m in less than ten seconds, as the recent Commonwealth Games demonstrated. However, as the world record stands at 9.58 seconds, the attention in recent years has turned to whether a human will be able to run 100m in less than nine seconds one day.*

Our thoughts, based on 20 years of investigating the biomechanics of sprinting, are "of course they can". There is no limit to human sprinting in sight yet. Humans have run competitively (with time records available) for only about 100 years. In the context of human evolution, this is far too short a period to analyse with a view of making long-term predictions for the future. Records are still being broken, and training and technology (for example, track surfaces and running spikes) are continuously developed further.

In fact, from Jim Hines' beating the ten-second barrier for the first time in 1968 to Maurice Green in 1999, the world record improved by 0.16 seconds in 31 years, but since then the record has been improved by 0.21 seconds in only ten years. This does not necessarily imply

that the development of the record is speeding up, just that we cannot consider human limits in a short-term perspective.

There have always been and there will always be humans who make new leaps in these kinds of records. To develop the argument against a set limit in human performance further, why would not Usain Bolt have a son who is just a bit taller, stronger and faster than Usain himself, and so on?

CONTINUED ON PAGE 68

\*Bioscience Journal has been granted permission to use this article, which first appeared on The Conversation at <http://theconversation.com>

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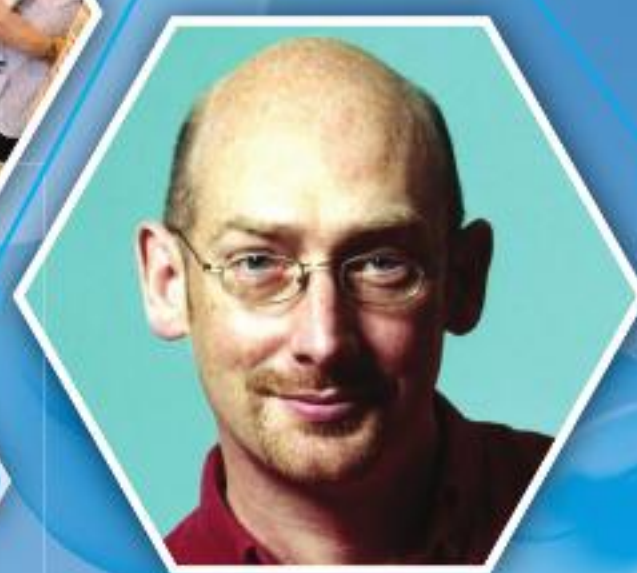
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## BETTER TRAINING AND TECHNIQUES

The issue of improving performance is also down to better training and improving running technique. In a recent scientific paper we highlighted the importance of powerful gluteus (buttock) muscles for the start performance in sprinting. Athletes and coaches can then train and strengthen these key muscle groups to get out of the starting blocks better.

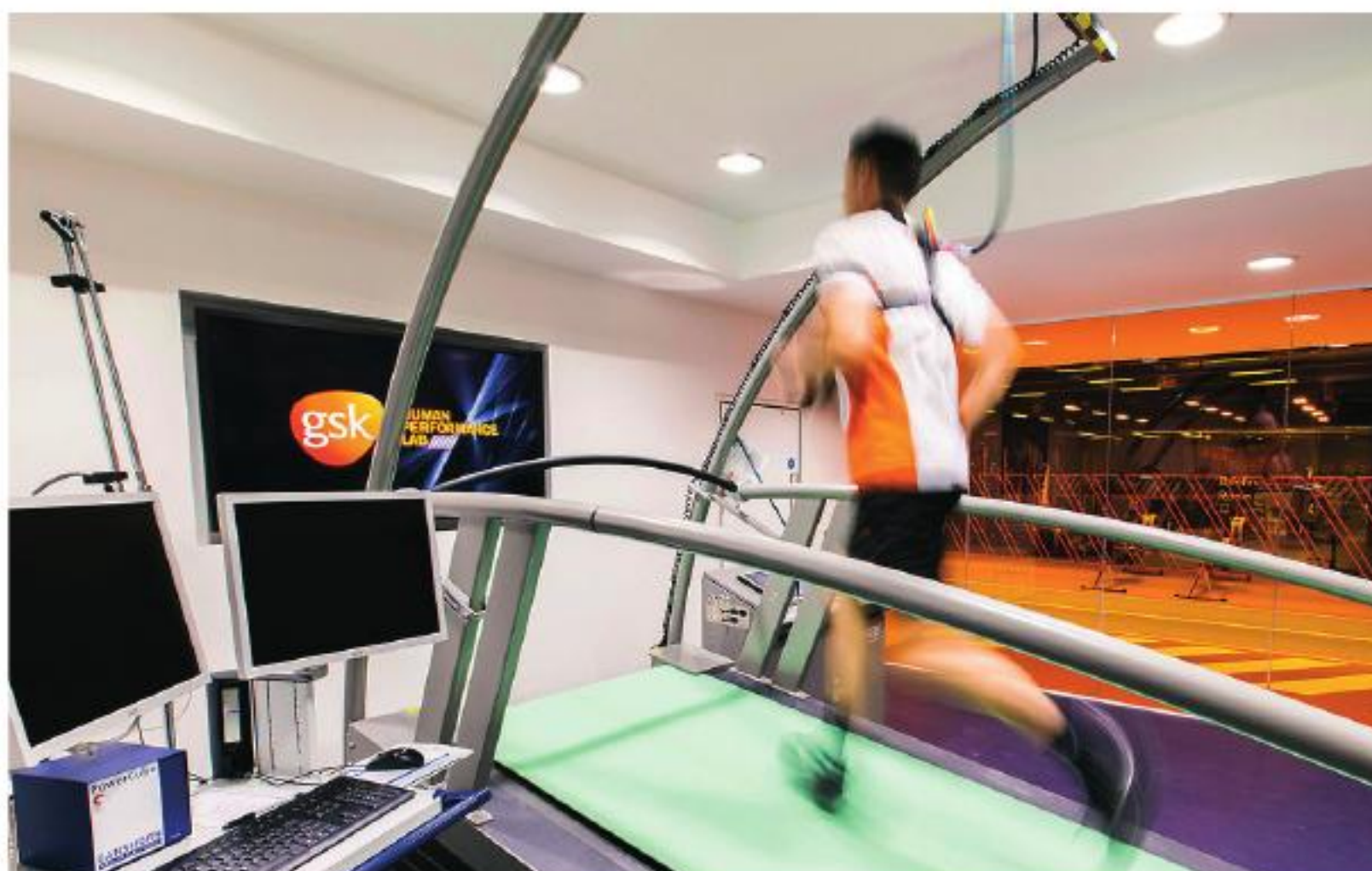
Overall, the sprinting velocity is a product of step length and step frequency. In his world record run in Berlin 2009, Usain Bolt ran at 12.4m/s in his fastest phase. He did this with a step length of 2.77m and step frequency of 4.49<sup>Hz</sup>.

For a human to run 100m in under nine seconds, this would require maximum velocity to reach about 13.2m/s. Such velocity would require, for example, step length to be 2.85m and step frequency 4.63<sup>Hz</sup> – just “modest” increases from Usain Bolt’s values.

But the progress is not so easy, as when athletes start to increase step length in the maximum velocity phase, it has a negative effect on step frequency. Longer steps take longer time to make and thus step frequency will go down and vice versa. Thus, it will likely take time before we see that kind of performance. The main issue is how much power (large forces in the shortest possible time) humans can produce and what the requirements are to achieve this.

## LONG STEPS AT A HIGH FREQUENCY

To produce long steps at a high frequency an athlete has to produce a huge amount of force (approximately 4.5 times body weight) in a very short period of time (around 0.1s). To do this they must maintain a very stiff leg and accelerate it into the ground at foot contact. Recent research has shown that it is this difference in the forces generated in the



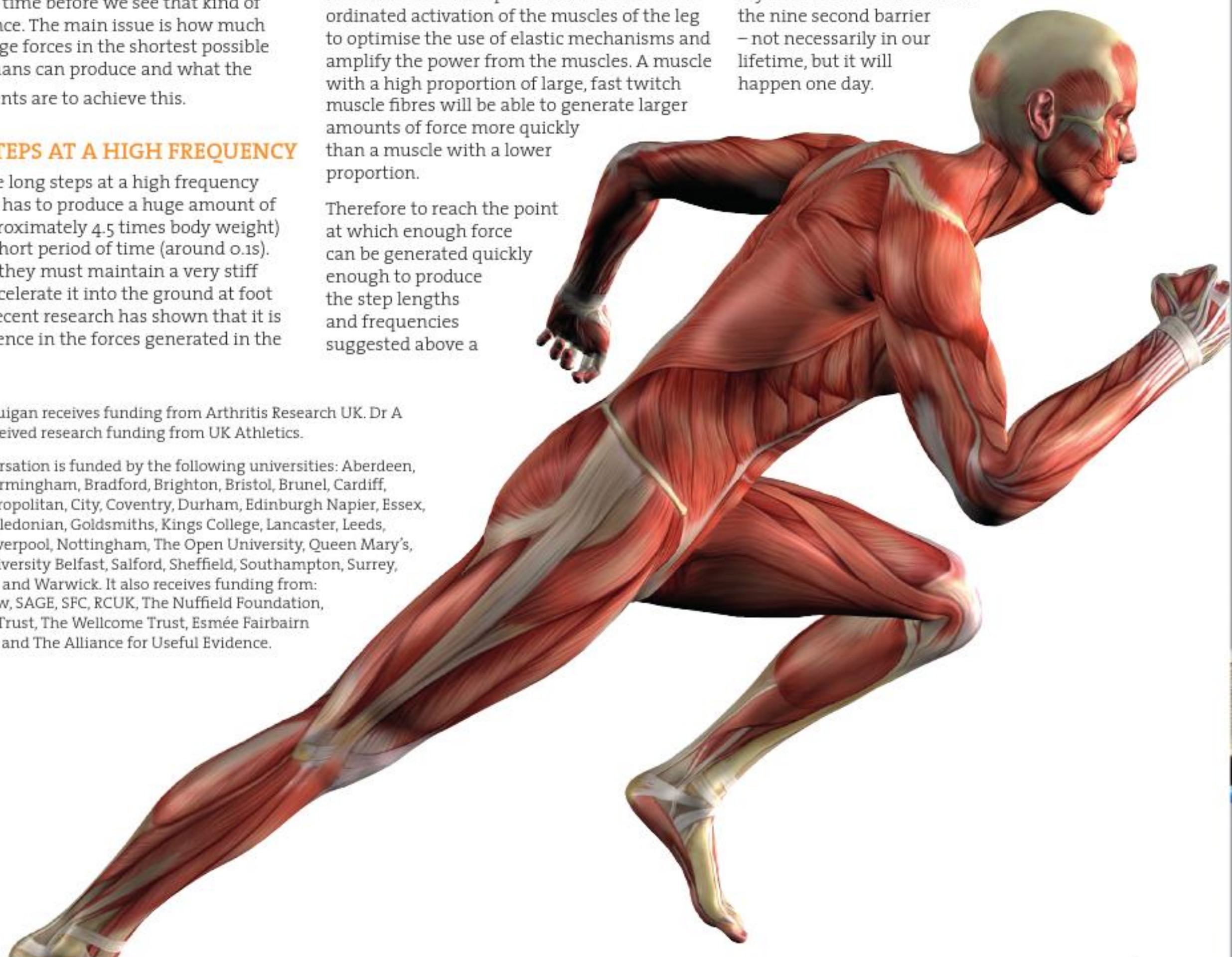
early part of the stance phase (just after foot contact) that distinguishes very fast sprinters from the less fast ones.

The ability to maintain a stiff limb is determined by how muscle force can be generated in the muscles of the leg. This in turn is a function of muscle size, the types of fibres which make up the muscles and the co-ordinated activation of the muscles of the leg to optimise the use of elastic mechanisms and amplify the power from the muscles. A muscle with a high proportion of large, fast twitch muscle fibres will be able to generate larger amounts of force more quickly than a muscle with a lower proportion.

Therefore to reach the point at which enough force can be generated quickly enough to produce the step lengths and frequencies suggested above a

combination of genetics and training would need to produce bum, thigh and calf muscles which are a little bit stronger and faster than the current best sprinters.

The record will start to plateau at some point and it will get harder and harder to outrun the previous record holder. But, it's safe to say that someone will break the nine second barrier – not necessarily in our lifetime, but it will happen one day.



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# How do bioscience companies ensure a strong talent pipeline for the future?

*The UK science industry is facing a national shortage of highly skilled workers, an issue linked previously to STEM subjects being a less favourable option at A Level.*

But the tides are changing; this year saw Maths become the most popular A Level, swiftly followed by Biology and Chemistry. Yet employers are still facing a significant skills gap. In response to this, efforts are being made to improve the employability of first-time job seekers, equipping them with the essential practical knowledge and work experience.

A recent CBI Education and Skills Survey<sup>1</sup> found that the current education system fails to provide young people with the skills and knowledge necessary to succeed in the workplace. It stated that 39% of employers have reported difficulties recruiting STEM proficient staff.

Industrial placements are an essential step on the career ladder in many science using occupations and are useful not only

for students but also employers. Hosting a placement enables an employer to create links with universities which can offer longer-term possibilities including research opportunities and strong brand recognition amongst students. An employer can benefit from accessing an enthusiastic member of staff with no long term commitments. Not to mention that investing in industrial placements will provide the scientists of the future with the practical skills necessary to succeed in graduate positions.

Despite these clear benefits, there has been a marked decline in the number of employers offering industrial placements. The time constraints associated with recruitment is often identified as a barrier from hiring a new member of staff.

With the Government recognising the importance of closing the skills gap and attracting more science graduates into science careers, Cogent has secured funding to set up an initiative to retain the highly talented undergraduate talent pool. Research conducted by the Department for Business, Innovation and Skills identified that only 11% of STEM graduates definitely do not want to take up a STEM career. Cogent's placement service supports employers of all sizes in developing

their placement service and improving the employability skills of students and graduates with the hope that more science graduates can secure careers in the sector after graduation.

Cogent offers a recruitment and managed placement service to all employers wanting to engage in industrial placements, and has developed extensive links with universities across the country to tap into top undergraduate and graduate talent. For employers who are unable to increase headcount, Cogent can employ the student on behalf of the employer and manage all aspects of HR and payroll thus removing all barriers to recruitment.

With this industrial placements initiative, there will be more opportunities available for students and graduates to gain the hands on experience they are currently lacking, helping to reduce the skills gap and inspiring more students to pursue a career in science. Employers taking part will contribute to the development of a future talent pool with the capabilities that the science sector needs for years to come.

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1. CBI (2014) Gateway to Growth: Education and Skills Survey 2014, London: CBI/Pearson.



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